Bp number: 01-016-23n

App number: 2001-72XRAB Begin movement: 2/09/01 Received: 1/16/01 End movement: 2/09/02 Institution: Monsanto 2/09/01 Begin release: Recipient: Wheat End release: 2/09/02 Status: Pending Acre: 10.00 Effective date: 2/15/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield MO Fax: 636-737-7085 Initial Assign Bp number and initial data entry [Review by biotechnologist [Letter of notification to State | ed - ex 3. [] State response O/d Loc Site Reg Interstate *Dest*HI *WR * Interstate *Dest*KS *SCR *] Interstate *Dest*MO Г Interstate *Dest*MT Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*MT *WR Release *MT 2*WR [] Enter genes into database Letter of acknowledgement/denial/withdraw [Y Enter final data into database [] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker,

neason for tandiness (KS) did met respond

Does not qualify



Monsanto Reference ID

2001-72XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-23n

1. USDA Reference Number

2. Applicant Reference Number 2001-72XRAB

3. Applicant/Responsible Party

1

(b) (6), (b) (7)(C)

Phone FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 10, 2001

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Re	ference	ID
-------------	---------	----

2001-72XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [

(b)(4)

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

(b)(4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-72XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

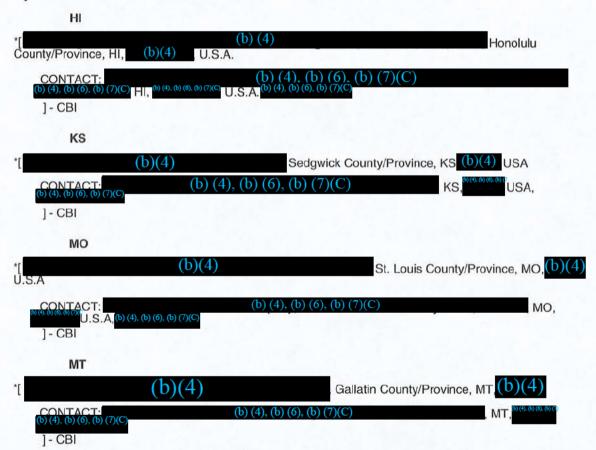
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DESTINATION:

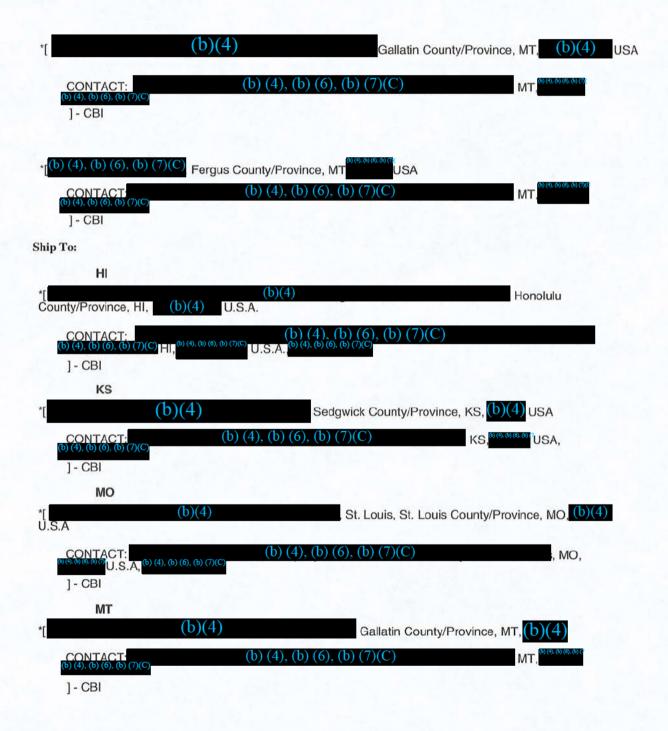
HI, KS, MO, MT

HI, KS, MO, MT

Ship From:

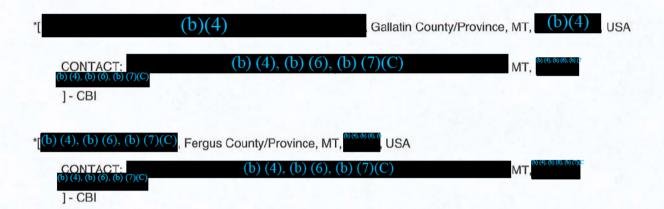


Monsanto Reference ID 2001-72XRAB



Page 4 of 7

Monsanto Reference ID 2001-72XRAB



Monsanto Reference ID 2001-72XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (2)

MT

(b)(4)

Gallatin County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b)(4),(b)(6),(b)(7)(0)
MT,(b)(4),(b)(6),(b)(7)(0)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Fergus County/Province, MT, USA, 5 acres.

] - CBI



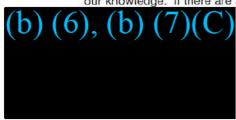
Monsanto Reference ID 2001-72XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-71XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-71XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-71XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 10, 2001

Monsanto Reference ID

2001-72XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-23n

63198

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-72XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

ON

Phone

FAX EMail (b) (6), (b) (7)(C)

636/737-7085 (b) (6), (b) (7)(0

monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-72XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-72XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, MT

HI, KS, MO, MT

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

MT

CBI Deleted] -- *Gallatin County/Province, MT

CBI Deleted] -- *Gallatin County/Province, MT, USA

Page 3 of 7

Monsanto Reference ID 2001-72XRAB

```
[ CBI Deleted ] -- *Fergus County/Province, MT, USA
Ship To:
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          MT
[ CBI Deleted ] -- *Gallatin County/Province, MT
[ CBI Deleted ] -- *Gallatin County/Province, MT, USA
```

Monsanto Reference ID 2001-72XRAB

[CBI Deleted] -- *Fergus County/Province, MT, USA

Monsanto Reference ID

2001-72XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (2)

MT

CBI Deleted] -- Gallatin County/Province, MT, USA, 5 acres

[CBI Deleted] -- Fergus County/Province, MT, USA, 5 acres



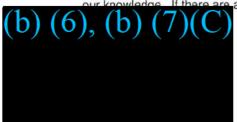
Monsanto Reference ID 2001-72XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001



Phone FAX

EMail

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 10, 2001

Monsanto Reference ID

2001-72XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-23n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-72XRAB
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(b) (6), (b)(7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

b) (6), (b) (7)(**C**

636/737-7085

monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

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Phenotype:

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Cultivar/Variety Bobwhite

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PV-TXGT10

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Monsanto Reference ID

2001-72XRAB

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Disarmed Agrobacterium tumefaciens

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ORIGIN:

DESTINATION:

HI, KS, MO, MT

HI, KS, MO, MT

Ship From:

HI

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KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI Deleted] -- *Gallatin County/Province, MT, USA

Page 3 of 7

Monsanto Reference ID 2001-72XRAB

```
[ CBI Deleted ] -- *Fergus County/Province, MT, USA
Ship To:
          н
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
 [ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
 [ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          MT
 [ CBI Deleted ] -- *Gallatin County/Province, MT
 [ CBI Deleted ] -- *Gallatin County/Province, MT, USA
```

Monsanto Reference ID 2001-72XRAB

[CBI Deleted] -- *Fergus County/Province, MT, USA

Monsanto Reference ID

2001-72XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (2)

MT

CBI Deleted] -- Gallatin County/Province, MT, USA, 5 acres

[CBI Deleted] -- Fergus County/Province, MT, USA, 5 acres

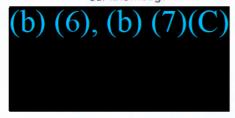


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CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Monsanto Reference ID 2001-72XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-23n

Applicant #: 2001-72XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO MT

Release destination: N

MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RE	ESPONSE TO NOTIFICATION
State concurs with APHIS of	determination.
State DOES NOT CONCUR and	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281 January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-016-23n Applicant #: 2001-72XRAB

Received: January 16, 2001 Effective: February 15, 2001

Institution: Monsanto Recipient: Wheat

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Sincerely,

15

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION _____State concurs with APHIS determination. _____State DOES NOT CONCUR and offers the following reasons: Name of State official: Signature: Date: Rptloc01/R4

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-23n

Applicant #: 2001-72XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Recipient:

Whoat

Institution: Monsanto

MO MIII

Wheat

Interstate destination: HI KS MO MT

Release destination: M

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151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
State concurs wi	th APHIS determination.
State DOES NOT C	ONCUR and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rpt1oc01/R4

Vacant , Administrator Agriculture Sciences Division Montana Department of Agriculture P.O. Box 200201 Helena, MT 59620-0201

January 17, 2001

Dear :

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-23n

Applicant #: 2001-72XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Recipient:

Wheat

Institution: Monsanto
Interstate destination: HI KS MO MT

Recipient. Will

Release destination:

MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,



Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

	STATE RESPONSE TO NOTIFICATION
	_State concurs with APHIS determination.
	_State DOES NOT CONCUR and offers the following reasons:
Name o	of State official:
Signa	cure:
Date:	
State	Potloc01/P4



Animal and Plant Health Inapaction Service 4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-23n

Applicant #: 2001-72XRAB

Received:

January 16, 2001

MT

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE	TO	NOTIFICATION
----------------	----	--------------

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:

Name of State

cada

Signature:

Date: 15 February

State:

Hawai

Rptloc01/R4

APHS - Protecting American Agriculture



Animal and Plane Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-23n

Applicant #: 2001-72XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

h .	STATE RESPONSE TO NOTIFICATION
State conc	urs with APHIS determination.
State DOES	NOT CONCUR and offers the following reasons:
Signature:	(b) (6), (b) (7)(C)
Date: 1/3//01	
State: MO	Rptloc01/R4

FEB 5 2001



An Equal Opportunity Employer OR120018 BR_007044



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Vacant , Administrator Agriculture Sciences Division Montana Department of Agriculture P.O. Box 200201 Helena, MT 59620-0201

January 17, 2001

Dear :

Enclosed is notification 01-016-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-23n

Applicant #: 2001-72XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

1			STATE	RESPONSE '	TO NOTI	FICATION	-8
	_State	concurs	with APHIS	determina	ation.	\$. t.	
Name o		DOES NOT	concur and	d offers Witha		lowing r	easons:
	ure:		b), (b) (7)(C)			
Date:_	1/20	101	41 The ex	7	¥ .	"	



State: NWYUWYW

Rptloc01/R4

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release Notification no. 01-016-23n (2001-72XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

SI

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- L. Witham, Montana Dept. of Agric., Helena, MT
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-016-23n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

001 OK

916367377865

038/038 00:08:28

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Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ. SCR, WR, Sacramento, CA



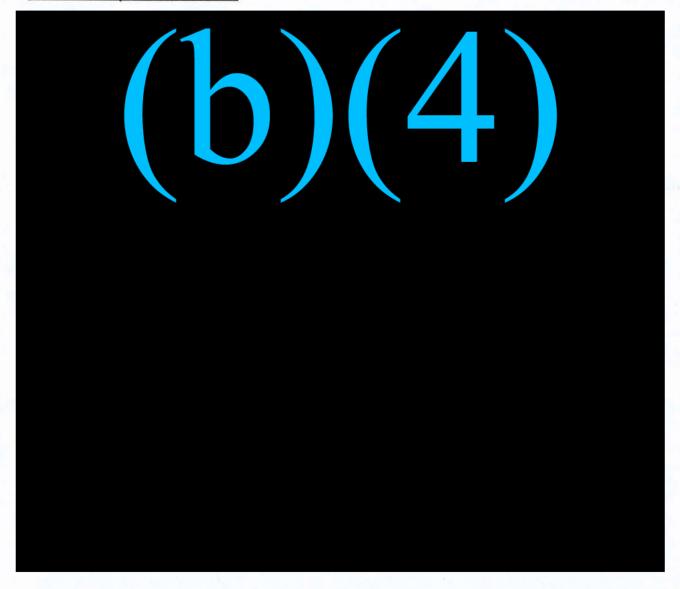
2001 Wheat Field Test Report USDA #01-016-23n Monsanto #2001-72XRAB

October 2, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	State
2147303789	Gallatin County	MT
2147303550	Fergus County	MT

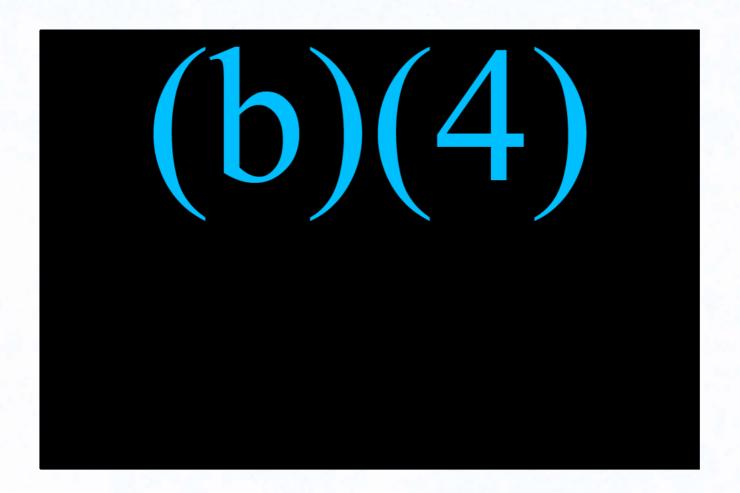
Gallatin County/MT (2147303789)





Fergus County/MT (2147303550)





CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018 BR 007052

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-016-23n Monsanto #2001-72XRAB

October 2, 2002

Biotech Field Compliance Team Monsanto Company

Location 2147303789 County

State

2147303550

Gallatin County Fergus County

MT MT

Gallatin County/MT (2147303789)

Planting Date:

04/23/2001

Destruct Date:

07/03/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date:

05/02/2001

Harvest Date:

08/31/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Fergus County/MT (2147303550)

Planting Date: 04/19/2001

Harvest Date: 08/14/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bp number: 01-016-24n

App number: 2001-73XRAB Begin movement: 2/09/01 Received: 1/16/01 End movement: 2/09/02 Institution: Monsanto Begin release: 2/09/01 Recipient: Wheat End release: 2/09/02 Status: Pending Acre: 5.00 Effective date: 2/15/01 CBI status: CBI HT - Glyphosate tolerant Phenotype: Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield, MO Telephone: (b) (6), (b) (7)(C Fax: 636-737-7085 Initial [Assign Bp number and initial data entry [] /Review by biotechnologist [/] Letter of notification to State | cd - ex 3. [] State response O/d Loc Site Reg Interstate *Dest*HI * *WR * Interstate *Dest*KS *SCR * [1 Interstate *Dest*MO *SCR * Interstate *Dest*MT *WR * Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*MT *WR Release *MT 1*WR [I Enter genes into database Letter of acknowledgement/denial/withdraw [26/01] Enter final data into database If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify reason for tardiness - (KS) alid not respond



Monsanto Reference ID 2001-73XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-24n

1. USDA Reference Number

2. Applicant Reference Number 2001-73XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

10

63198

Phone

FAX

EMail

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 10, 2001

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

b) (6), (b) (7)(**C**

636/737-7085

@monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID 2001-73XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b)(4)

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b)(4)

(b)(4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-73XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

ship up to 4000 pounds of wheat seed to and from each location.

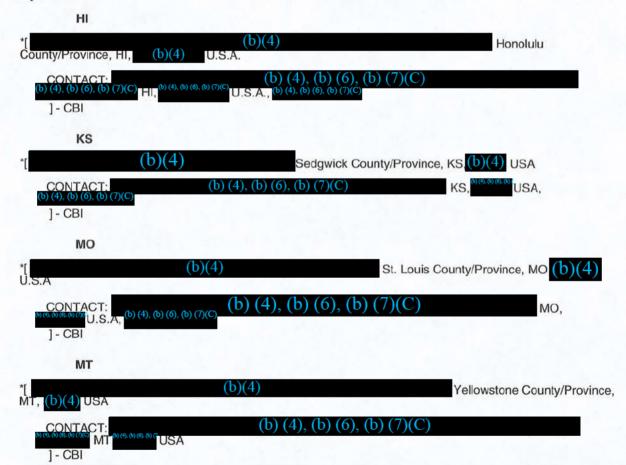
ORIGIN:

DESTINATION:

HI, KS, MO, MT

HI, KS, MO, MT

Ship From:



Monsanto Reference ID 2001-73XRAB

Ship To: HI (b)(4)*[County/Province, HI, Honolulu (b)(4)(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A. 1-CBI KS (b)(4)Sedgwick County/Province, KS (b)(4) USA 1-CBI MO (b)(4)St. Louis County/Province, MO, (b)(4) CONTACT: MO, (b) (4), (b) (6), (b) (7)(C)] - CBI MT (b)(4)Yellowstone County/Province, (b)(4) USA (1.000.0 USA] - CBI

Monsanto Reference ID

2001-73XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[(b)(4) Yellowstone County/Province, MT, USA, 5 acres.

] - CBI



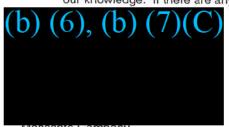
Monsanto Reference ID 2001-73XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company

January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-73XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-73XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-73XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID

2001-73XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-24n

1. USDA Reference Number

2. Applicant Reference Number 2001-73XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 10, 2001

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID 2001-73XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-73XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, MT

HI, KS, MO, MT

Ship From:

Ш

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

MT

[CBI Deleted] -- *Yellowstone County/Province, MT, USA

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

Page 3 of 6

Monsanto Reference ID 2001-73XRAB

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

MT

[CBI Deleted] -- *Yellowstone County/Province, MT, USA

Monsanto Reference ID

2001-73XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

CBI Deleted] -- Yellowstone County/Province, MT, USA, 5 acres





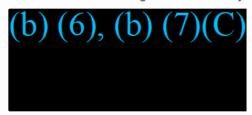
MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-73XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001



Monsanto Reference ID 2001-73XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-24n

1. USDA Reference Number

2. Applicant Reference Number 2001-73XRAB

3. Applicant/Responsible Party

Phone

(b) (6), (b) (7)(C)

FAX EMail 636/737-7085

(b) (6), (b) (7)(C) monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 10, 2001

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

MO

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-73XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-73XRAB

HI

Page 3 of 6

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

7. Mode of Transfo	rmation Disarmed Agrobacterium tumefacie	ens
8. Introduction	Interstate Movement and Release	
ship up to 4000 p	ounds of wheat seed to and from each location.	
ORIGIN:	DESTINATIO	N:
HI, KS, MO, M	T HI, KS, MO	TM ,C
Ship From:		
н		
[CBI Deleted] *Honolulu County/Province, HI, U.S.A.	
KS		
[CBI Deleted] *Sedgwick County/Province, KS, USA	
МО		
[CBI Deleted] *St. Louis County/Province, MO, U.S.A	
MT		
] *Yellowstone County/Province, MT, USA	
[CBI Deleted	j Yellowstone County/Province, MT, USA	
Ship To:		



Monsanto Reference ID 2001-73XRAB

KS
[CBI Deleted] -- *Sedgwick County/Province, KS, USA
MO
[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A
MT
[CBI Deleted] -- *Yellowstone County/Province, MT, USA

Monsanto Reference ID

2001-73XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

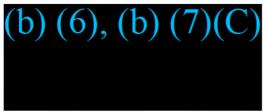
[CBI Deleted] -- Yellowstone County/Province, MT, USA, 5 acres



Monsanto Reference ID 2001-73XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-24n

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Wheat

Recipient:

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RES	SPONSE TO NOTIFICATION
State concurs with APHIS de	etermination.
State DOES NOT CONCUR and c	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-24n

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO MT

Release destination: N

MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

15

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RES	SPONSE TO NOTIFICATION
State concurs with APHIS de	etermination.
State DOES NOT CONCUR and c	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-24n

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Recipient:

Wheat

Institution: Monsanto

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION State concurs with APHIS determination. State DOES NOT CONCUR and offers the following reasons: Name of State official:_____ Signature:_____ Date:____ State:____ Rptloc01/R4

Vacant , Administrator Agriculture Sciences Division Montana Department of Agriculture P.O. Box 200201 Helena, MT 59620-0201 January 17, 2001

Dear :

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-24n

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT

Release destination:

Mili

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RES	PONSE TO NOTIFICATION
State concurs with APHIS de	termination.
State DOES NOT CONCUR and or	ffers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rotloc01/R4



Animat and Plant Health Inspection Service

4700 River Road Riverdala, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bo number

01-016-24n

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT

Release destination:

MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(6), (b) (7)(0

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:

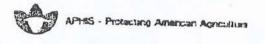
Name of State off

Signature:

Date: 15 February 2001

State:

Rptloc01/R4



FEB 1 6 2001



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-241

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Recipient: W

Wheat:

Interstate destination: HI KS MO MT

Release destination:

MAN 1977

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

. cc: R. Elliston, PPQ, Fort Collins, CO

\0	STATE RESPONSE TO NOTIFICATION
State concurs with	APHIS determination.
State DOES NOT CON	CUR and offers the following reasons:
Name of State official	Michael E. Brown
Signature: (b) (6	(b) (7)(C)
Date: 1/3//01	
State: MO	Rpt1oc01/R4

APMS - Protecting American Agriculture

FEB 5 2001



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Vacant , Administrator Agriculture Sciences Division Montana Department of Agriculture P.O. Box 200201 Helena, MT 59620-0201

January 17, 2001

Dear :

Enclosed is notification 01-016-24n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-24n

Applicant #: 2001-73XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO MT

Release destination:

MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

S	TATE RESPONSE	TO NOTIFICATI	ON	8
State concurs with A	APHIS determi	nation.	· · · · ·	51
State DOES NOT CONC	OR and offers	the following	reason	ıs:
Name of State official:	ori With	am	Y +.	
signature: (b) (6), (b)	(7)(C)		10	
Date: 1/26/01	10 E			
state: Montana	# 25 /5 W	. Rptloc01	L/R4.	(6)



APHS - Protecting American Acresition

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-016-24n (2001-73XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

SI

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- L. Witham, Montana Dept. of Agric., Helena, MT
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-016-24n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

991 OK a

916367377085

038/038 00:08:28

– skokokok –



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

pear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Flant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT T. Wessels, Washington Dept. of Agric., Olympia. WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA



2001 Wheat Field Test Report USDA #01-016-24n Monsanto #2001-73XRAB

August 30, 2002

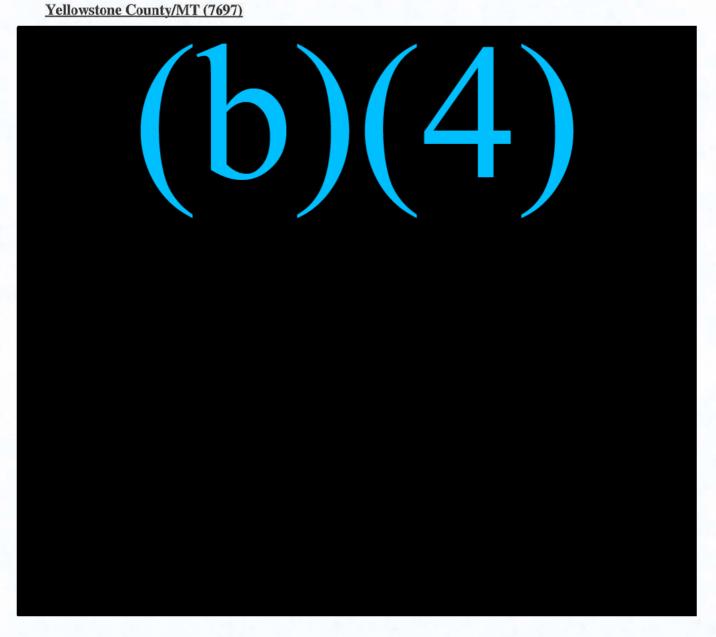
Biotech Field Compliance Team Monsanto Company

Location 7697

County

Yellowstone County

State MT



(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-016-24n Monsanto #2001-73XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

7697

Yellowstone County

MT

Yellowstone County/MT (7697)

Planting Date:

03/23/2001

Harvest Date:

08/21/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bp number: 01-016-25n

App number: 2001-74XRAB Begin movement: 2/09/01 Received: 1/16/01 2/09/02 End movement: Institution: Monsanto Begin release: 2/09/01 Recipient: Wheat End release: 2/09/02 Status: Pending Acre: 15.00 Effective date: 2/15/01 CBI status: CBI HT - Glyphosate tolerant Phenotype: Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip: Chesterfield, MO (b) (6), (b) (7)(C Fax: 636-737-7085 Initial [Assign Bp number and initial data entry Review by biotechnologist [Y Letter of notification to State red ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR * Interstate *Dest*KS *SCR * E] Interstate *Dest*MO [1 Interstate *Dest*MT *WR * Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*MT *WR Release *MT 3*WR Γ] [1 Enter genes into database Letter of acknowledgement/denial/withdraw (10)006/6] Enter final data into database [] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify

nearon for tandimens - (KS) did not respond



Monsanto Reference ID 2001-74XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-25n

1. USDA Reference Number

2. Applicant Reference Number 2001-74XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 10, 2001

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety bobwhite

Monsanto Reference	ID
2001-74XRAB	

designation of transformed line:

33391

Constructs: PV-T

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-74XRAB

designation of transformed line:

TA-S0317, TA-SO635, TA-SO1081, TA-S2520, TA-S5450,

CBI

CBI

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [(b)(4) (b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b)(4)

Monsanto Reference ID 2001-74XRAB

designation of transformed line:

TA-S9240, TA-S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-74XRAB

designation of transformed line:

TA-S7535, YA-S7890, TA-S9512, TA-S10430

Constructs: F

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 --

(h)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-74XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

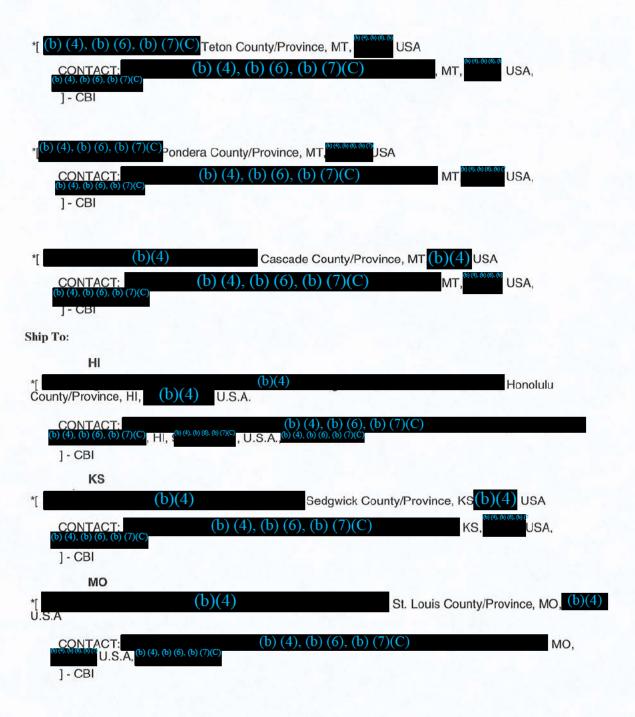
8. Introduction

Interstate Movement and Release

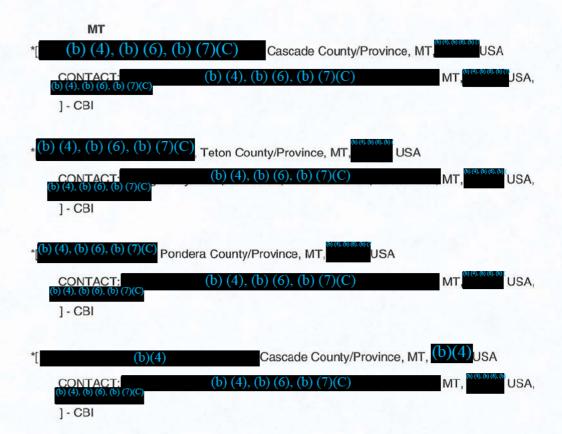
Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN: **DESTINATION:** HI, KS, MO, MT HI, KS, MO, MT Ship From: HI Honolulu County/Province, HI, (b)(4)U.S.A. b) (4), (b) (6), (b) (7)(C) U.S.A. 1 - CBI KS (b)(4)Sedgwick County/Province, KS(b)(4) USA CONTACT: (b) (4), (b) (6), (b) (7)(C)] - CBI MO *[U.S.A St. Louis County/Province, MO, (b)(4) (b) (4), (b) (6), (b) CONTACT:] - CBI MT (b) (4), (b) Cascade County/Province, MT CONTACT: (b) (4), (b) (6), (b) (7)(C) 1-CBI

Monsanto Reference ID 2001-74XRAB



Monsanto Reference ID 2001-74XRAB



Monsanto Reference ID

2001-74XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (3)

MT

(b) (4), (b) (6), (b) (7)(C) Cascade County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: MT, MG. (0) (4), (0) (6), (0) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: MT, 104-0100 USA, 104-0-0-0-0-0-0

(b) (4), (b) (6), (b) (7)(C

] - CBI



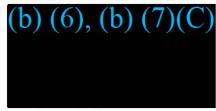
Monsanto Reference ID 2001-74XRAB

9. Certification

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

MONSANTO COMPANY

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-74XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-74XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-74XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 10, 2001

Monsanto Reference ID 2001-74XRAB

5

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-25n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-74XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

FAX

Phone

636/737-7085

o) (6), (b) (7)(**C**

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

НТ

Phenotype:

Glyphosate tolerant

Cultivar/Variety bobwhite

Monsanto Reference ID 2001-74XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-74XRAB

designation of transformed line:

TA-S0317, TA-S0635, TA-S01081, TA-S2520, TA-S5450,

Constructs:

PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID 2001-74XRAB

designation of transformed line:

TA-S9240, TA-S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-74XRAB

designation of transformed line:

TA-S7535, YA-S7890, TA-S9512, TA-S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-74XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, MT

HI, KS, MO, MT

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

MT

CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Teton County/Province, MT, USA

Page 6 of 10

Monsanto Reference ID 2001-74XRAB

```
[ CBI Deleted ] -- *Pondera County/Province, MT, USA
 [ CBI Deleted ] -- *Cascade County/Province, MT, USA
Ship To:
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          MT
[ CBI Deleted ] -- *Cascade County/Province, MT, USA
```

Monsanto Reference ID 2001-74XRAB

- [CBI Deleted] -- *Teton County/Province, MT, USA
- [CBI Deleted] -- *Pondera County/Province, MT, USA
- [CBI Deleted] -- *Cascade County/Province, MT, USA

Monsanto Reference ID 2001-74XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (3)

MT

[CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres

[CBI Deleted] -- Teton County/Province, MT, USA, 5 acres

[CBI Deleted] -- Pondera County/Province, MT, USA, 5 acres



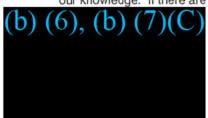
MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-74XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001



Phone

FAX

EMail

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 10, 2001

Monsanto Reference ID 2001-74XRAB

Permit Unit

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4700 River Rd.

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01-016-25n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-74XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MC

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

636/737-7085

@monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety bobwhite

Monsanto Reference ID 2001-74XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene. CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBIDELETED

Monsanto Reference ID

2001-74XRAB

designation of transformed line:

TA-S0317, TA-SO635, TA-SO1081, TA-S2520, TA-S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBIDELETED

Monsanto Reference ID

2001-74XRAB

designation of transformed line:

TA-S9240, TA-S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-74XRAB

designation of transformed line:

TA-S7535, YA-S7890, TA-S9512, TA-S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELENTED

Monsanto Reference ID 2001-74XRAB

7.	Mc	ode of Transfo	rmation	Disarmed Agroba	cterium tumefaciens
8.	Int	roduction		Interstate Movem	100
	Ship up to 4000 pounds of wheat			at seed to and from ea	ch location.
	OF	RIGIN:			DESTINATION:
	Н	I, KS, MO, M	Т		HI, KS, MO, M
	Ship	From:			
		н			
	[CBI Deleted] *Honolulu	County/Province, HI,	U.S.A.
		KS			
13	1] *Sedgwick	k County/Province, KS	S, USA
	10).				
		МО			
	[CBI Deleted] *St. Louis	County/Province, MO	, U.S.A
	1965	MT		0	
	[CBI Deleted] Cascade	County/Province, MT	, USA
	[CBI Deleted] *Teton Co	ounty/Province, MT, U	SA

Page 6 of 10

CBI-DELETED

Monsanto Reference ID 2001-74XRAB

```
[ CBI Deleted ] -- *Pondera County/Province, MT, USA
[ CBI Deleted ] -- *Cascade County/Province, MT, USA
Ship To:
          HI
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
 [ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          MT
[ CBI Deleted ] -- *Cascade County/Province, MT, USA
```

CHS In D Land Low I for Do

Monsanto Reference ID 2001-74XRAB

- [CBI Deleted] -- *Teton County/Province, MT, USA
- [CBI Deleted] -- *Pondera County/Province, MT, USA
- [CBI Deleted] -- *Cascade County/Province, MT, USA

CBIDELETED

Monsanto Reference ID

2001-74XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (3)

MT

[CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres

[CBI Deleted] -- Teton County/Province, MT, USA, 5 acres

[CBI Deleted] -- Pondera County/Province, MT, USA, 5 acres

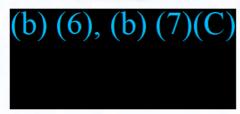


CBI-DELETED

Monsanto Reference ID 2001-74XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001 Mr. Myron Isherwood Jr., Manager Plant Ouarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Recipient:

Wheat

Institution: Monsanto

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RES	PONSE TO NOTIFICATION	
State concurs with APHIS de	termination.	
State DOES NOT CONCUR and o	offers the following reasons:	
Name of State official:		
Signature:		
Date:		
State:	Rptloc01/R4	

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RE	SPONSE TO NOTIFICATION
State concurs with APHIS de	etermination.
State DOES NOT CONCUR and	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001 Effective: February 15, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION State concurs with APHIS determination. State DOES NOT CONCUR and offers the following reasons: Name of State official: Signature: Date: Rptloc01/R4 State:

Vacant , Administrator Agriculture Sciences Division Montana Department of Agriculture P.O. Box 200201 Helena, MT 59620-0201

January 17, 2001

Dear :

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001

Effective: February 15, 2001 Recipient: Wheat

Institution: Monsanto Recipient:

Interstate destination: HI KS MO MT

Release destination:

HI KS MO MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

15/

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE R	ESPONSE TO NOTIFICATION
State concurs with APHIS	determination.
State DOES NOT CONCUR and	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO MT

Release destination:

MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada Hawaii Dept. of Agriculture, 701 Ilalo St. Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Carol L.

Signature:

Date: 15 February 2001

State:

Rptloc01/R4





Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat:

Interstate destination: HI KS MO MT

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

- ^		STATE RESPON	SE TO NOTI	FICATION	
	ate concurs w	th APHIS determ	mination.		
	ate DOES NOT (CONCUR and offe	the fol	lowing reason	ons:
Signature	(h) (6), (b) (7)(C)		
Date: 0)	125/01	141			
State:	MO		RE	tloc01/R4	

JAN 3 0 2001



APrilS - Protecting American Agricultura

An Equal Opportunity Employee OR120018 BR 007134



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Vacant , Administrator Agriculture Sciences Division Montana Department of Agriculture P.O. Box 200201 Helena, MT 59620-0201

January 17, 2001

Dear :

Enclosed is notification 01-016-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-25n

Applicant #: 2001-74XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO MT

Release destination: ידיואן

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

,	STATE RESPONSE TO NOTIFICATION	
	_State concurs with APHIS determination.	1
	State DOES NOT CONCUR and offers the following reasons:	
Name o	E State official LOVI WITHAM	
Signat	ure: (b) (6), (b) (7)(C)	,
Date:	1/26/01	
State:	Mortana Rotloco1/R4	



(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b)(6),(b)(7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-016-25n (2001-74XRAE)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

5

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- L. Witham, Montana Dept. of Agric., Helena, MT
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-016-25n

COMM. JOURNAL - MANAGEMENT DATE FEB-23-2001 HONDRING TIME 17:59 HONDRING HONDRING

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

001 OK

916367377085

038/038 00:08:28

– sokotokok –



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b)(7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear

(b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 6, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA



March 23, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

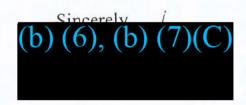
Ms. Dianne Hatmaker Animal and Plant Health Inspection Services Biotechnology and Scientific Services 4700 River Road, Unit 147 Riverdale, MD

Dear Ms. Hatmaker;

In reviewing several acknowledged wheat notification, a typing error was discovered in line numbers. The line numbers should be TA_S0317, TA_S0635, TA_01081, TA_S2520, TA_S5450, TA_9240, TA_S0719, TA_S7535, TA_S7890, TA_S9512, TA_S10430. These lines were submitted with a hyphen rather than an underscore. The affected notifications were

Monsanto #	USDA#
2001-65XRAB	01-017-02n
2001-74XRAB	01-016-25n
2001-64XRAB	01-017-01n
2001-144XRAB	01-017-12n
2001-201XRAB	01-022-15n

If you have any additional questions, please call me my telephone number is 636/737-6032.



cc: M. Isherwood Hawaii Dept. of Agric., Honolulu, HI

T. Sim, Kansas State Board of Agric. Topeka, Ks

M. Brown, Missouri Dept of Agric. Jefferson City, MO

- J. Griesbach, Oregon Dept. of Agric., Salem, Oregon
- T. Wessels, Washington Dept. of Agric., Olympia, WA
- R. Stokes, PPQ, WR, SCR, Sacramento, CA
- L. Witham, Montana Dept. of Agric., Helena, WA
- D. Nelson, North Dakota Dept. of Agric., Bismarch, ND
- K. Fridley, South Dakota Dept. of Agric., Pierre, SD

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

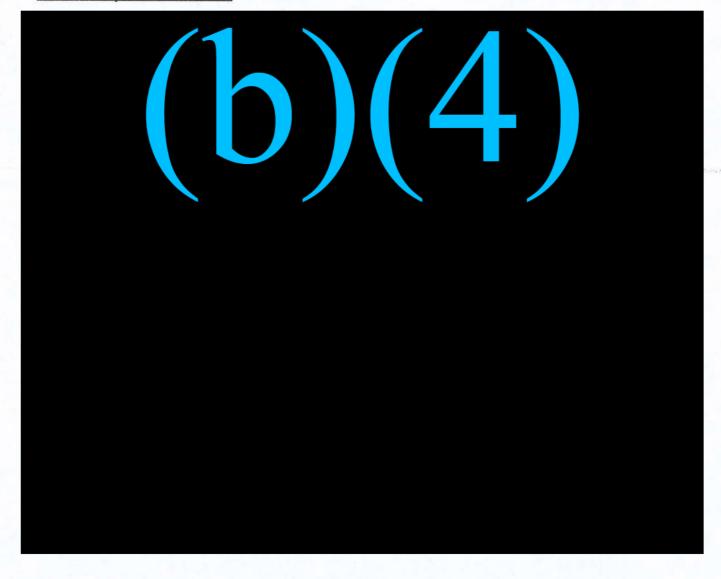
2001 Wheat Field Test Report USDA #01-016-25n Monsanto #2001-74XRAB

October 2, 2002

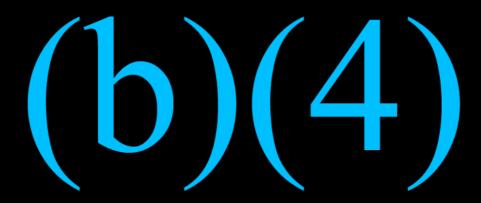
Biotech Field Compliance Team Monsanto Company

Location	County	State	
2147306798	Cascade County	MT	Not Planted
2147306799	Teton County	MT	
2147303362	Pondera County	MT	

Teton County/MT (2147306799)



Pondera County/MT (2147303362)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018 BR 007143

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report USDA #01-016-25n Monsanto #2001-74XRAB

October 2, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	State	
2147306798	Cascade County	MT	Not Planted
2147306799	Teton County	MT	
2147303362	Pondera County	MT	

Teton County/MT (2147306799)

Planting Date: 04/24/2001

Destruct Date: 06/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Pondera County/MT (2147303362)

Planting Date: 04/25/2001

Harvest Date: 08/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Notification Tracking Sheet

Bp number: 01-016-26n **===============**

App number: 2001-77XRAB Begin movement: Received: 1/16/01 End movement: Institution: Monsanto Begin release: End release: Recipient: Wheat Pending Status: Acre: Effective date: 2/15/01 CBI status:

Phenotype:

HT - Glyphosate tolerant

Comments: Resp person: Parsed name:

Address1: Address2:

Monsanto Company

700 Chesterfield Parkway N.

Address3: Address4:

2.

City/State/Zip: Chesterfield MO

Review by biotechnologist

(b) (6), (b) (7)(C Telephone: Fax: 636-737-7085 ________ Initial

[M Assign Bp number and initial data entry 1.

2/09/01

2/09/02

2/09/01

2/09/02

CBI

5.00

[I Letter of notification to State Led -ex 3.

[] State response

	O/d Loc	Sit	e Reg					-
Interstate	*Dest*HI	*	*WR	*	[]	[]
Interstate	*Dest*KS	*	*SCR	*	[]	[]
Interstate	*Dest*MO	*	*SCR	*	[]	[j
Interstate	*Dest*SD	*	*SCR	*	[]	[1
Interstate	*Orig*HI	*	*WR	*				
Interstate	*Orig*KS	*	*SCR	*				
Interstate	*Orig*MO	*	*SCR	*				
Interstate	*Orig*SD	*	*SCR	*				
Release	* *SD	*	1*SCR	*	[]	[1

Enter genes into database

Letter of acknowledgement/denial/withdraw

7. Enter final data into database 126/0/1

8. If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker,

Does not qualify

Meason for tardiness: (KS) did not respond

Monsanto Reference ID 2001-77XRAB

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-26n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-77XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HI

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-77XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- I

(b)(4)

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

(b)(4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-77XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, SD

HI, KS, MO, SD

Ship From:

(b)(4)County/Province, HI,

н

] - CBI

KS

Sedgwick County/Province, KS, (b)(4)USA

- CBI

MO

St. Louis County/Province, MO(b)(4)

CONTACT:

1 - CBI

SD

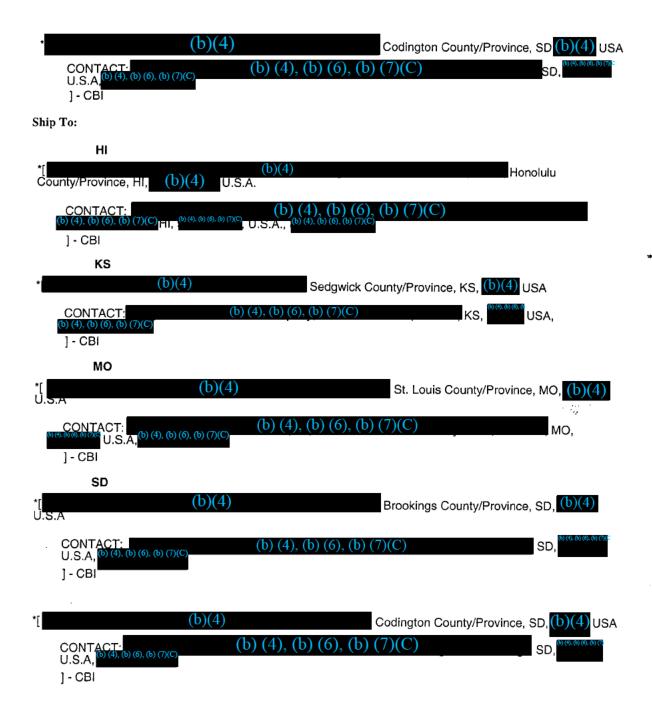
Brookings County/Province, SD, (b)(4)

CONTACT: U.S.A, (6) (4), (6) (6), (6) (7)(5)

] - CBI

Monsanto Reference ID

2001-77XRAB



Monsanto Reference ID 2001-77XRAB

Monsanto Reference ID

2001-77XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b)(4)

Codington County/Province, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) SD, (b) (6), (b) (7)(C) U.S.A (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

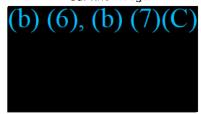
] - CBI



Monsanto Reference ID 2001-77XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-77XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 10, 2001

Monsanto Reference ID

2001-77XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-26n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-77XRAB
- 3. Applicant/Responsible Party

(b) (6), (b)(7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

МО

63198

Phone

FAX 636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-77XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-77XRAB

7. Mode of Transformation8. IntroductionShip up to 4000 pounds of wheat see	Disarmed Agrobacterium tumefaciens Interstate Movement and Release eed to and from each location.
ORIGIN: HI, KS, MO, SD	DESTINATION: HI, KS, MO, SD
Ship From:	711, NO, MO, OD
HI [CBI Deleted] *Honolulu Cou	unty/Province, HI, U.S.A.
KS [CBI Deleted] *Sedgwick Co	unty/Province, KS, USA
MO [CBI Deleted] *St. Louis Cou	nty/Province, MO, U.S.A
SD [CBI Deleted] *Brookings Co	unty/Province, SD, U.S.A

[CBI Deleted] -- *Codington County/Province, SD, USA

Page 3 of 6

Monsanto Reference ID 2001-77XRAB

Shi	ір То:	
]	HI CBI Deleted] *Honolulu County/Province, HI, U.S.A.
[KS CBI Deleted] *Sedgwick County/Province, KS, USA
[MO CBI Deleted] *St. Louis County/Province, MO, U.S.A
[SD CBI Deleted] *Brookings County/Province, SD, U.S.A
[CBI Deleted] *Codington County/Province, SD, USA

Monsanto Reference ID

2001-77XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

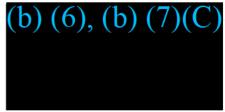
[CBI Deleted] -- Codington County/Province, SD, USA, 5 acres



Monsanto Reference ID 2001-77XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001



Monsanto Reference ID 2001-77XRAB

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-26n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-77XRAE
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C

FAX

636/737-7085

EMai!

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of introduction

interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

47

Phenotype:

Glypnosate tolerant

Cultivar/Variety Scownite

Monsanto Reference ID

2001-77XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [

(b)(4)

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b)(4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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Page 2 of 7

Monsanto Reference ID

2001-77XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

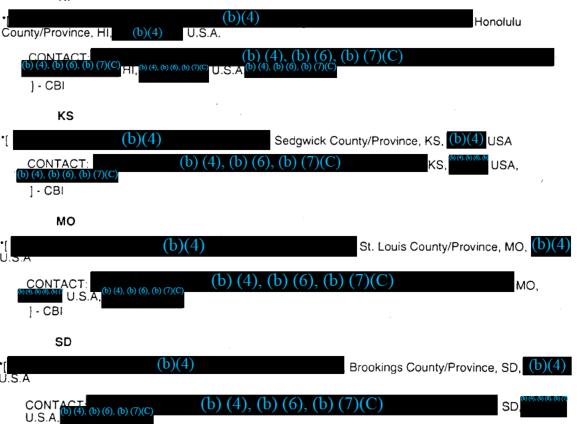
DESTINATION:

HI, KS, MO, SD

HI, KS, MO, SD

Ship From:

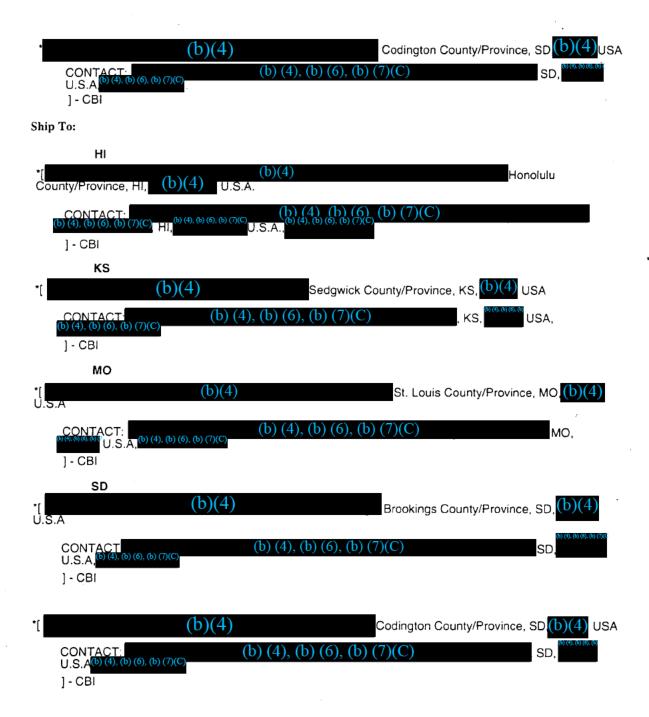
н



Page 3 of 7

] - CBI

Monsanto Reference ID 2001-77XRAB



Monsanto Reference ID 2001-77XRAB

Monsanto	Reference	ID
2001-77X	RAB	

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

(b)(4

Codington County/Province, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) SD, U.S.A, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

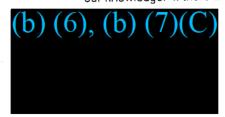


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MONSANTO COMPANY
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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

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GENE DESCRIPTION

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The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

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The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

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IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



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700 Chesterfield Pkwy North
Chesterfield, Missouri 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-26n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-77XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (b), (b) (7)(C₎

FAX EMail

636/737-7085

(b)(6),(b)(7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

MO

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

ΗT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-77XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyrity-territorial synthase gene (CP4) from an Agrobacterium species, strain 2014.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-77XRAB

·		
7. Mode of Transf	ormation Disarmed Agrobacter	ium tumefaciens
8. Introduction	Interstate Movement	and Release
Ship up to 4000	pounds of wheat seed to and from each ic	ocation.
ORIGIN:	_	DESTINATION:
HI, KS, MO, S	SD	HI, KS, MO, SI
Ship From:		
HI		
[CBI Deleted] *Honolulu County/Province, HI, U.S.	A.
KS		
[CBI Deleted] *Sedgwick County/Province, KS, US	A
MO	ı	
[CBI Deleted] *St. Louis County/Province, MO, U.S	. A
	•	
SD		
] *Brookings County/Province, SD, U.S	S A
(05/ 20/0/03	j Diodanigo Oddinyii Tovindo, OD, O.C	J./ \
[CBI Deleted] *Codington County/Province, SD, US	A

Page 3 of 6

Monsanto Reference ID 2001-77XRAB

Shi	р То:	
[HI CBI Deleted] *Honolulu County/Province, HI, U.S.A.
[KS CBI Deleted] *Sedgwick County/Province, KS, USA
[MO CBI Deleted] *St. Louis County/Province, MO, U.S.A
[SD CBI Deleted	} *Brookings County/Province, SD, U.S.A
ſ	CBI Deleted] *Codington County/Province, SD, USA

Monsanto Reference ID

2001-77XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (1)

SD

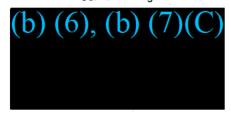
[CBI Deleted] -- Codington County/Province, SD, USA, 5 acres



Monsanto Reference ID 2001-77XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 10, 2001

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 Dear Mr. Isherwood Jr.:

January 17, 2001

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-26n

Applicant #: 2001-77XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION	
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following reasons:	
Name of State official:	
Signature:	
Date:	
State:	

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-26n

Applicant #: 2001-77XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787

or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

STATE RESPONSE TO NOTIFICATION	
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following reasons	3:
Name of State official:	
Signature:	
Date:	
State: Rptloc01/R4	

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-26n

Applicant #: 2001-77XRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons
Name of State official:
Signature:
Date:
State: Potloc01/P4

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 17, 2001

Dear Mr. Fridley:

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-26n

Applicant #: 2001-77XRAB

Received: Januar

January 16, 2001 Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

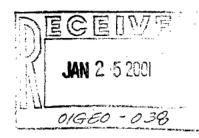
STATE RESPONS	SE TO NOTIFICATION
	,1 TO HOTIFICATION
State concurs with APHIS determ	mination.
State DOES NOT CONCUR and offer	s the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813



January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-26n

Applicant #: 2001-77XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely b) (6), (b) (

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE T	O NOTIFICATION
X State concurs with APHIS determina Hawaii Dept. of Agriculture, 701 I State DOES NOT CONCUR and offers t	tion: Please notify Ms. Carol Okada, lalo St., Honolulu, HI 96813. he following reasons:
Name of State official: Carol I. Okasignature: (b) (6), (b) (7)(C)	
Date: 15 February 2001	
State: <u>Hawaii</u>	Rptloc01/R4



Animai and Plant Health Inapection Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-26n

Applicant #: 2001-77XRAB

Received:

January 16, 2001

Effective:

Institution: Monsanto

Recipient:

February 15, 2001 Wheat

Interstate destination: HI KS MO SD

Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE DECRONGE TO MAN
STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
decemmination.
State DOES NOT CONCUR and offers the following reasons:
Name of State officials Missaul & Balb
$s_{ignature}$: (b) (6), (b) (7)(C)
Date: 2/2/0)
State: m
Rptloc01/R4

Protecting American Agriculture

5 2001 FE8



Animal and Plant Health Inspection Service

4700 River Road Riverdala, MD 20737



Mr. Kevin Fridley Division of Agricultural Services South Dakota Department of Agriculture Foss Building-523 East Capitol Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 01-016-26n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-016-26n Received: January 15, 2001

Applicant #: 2001-77XRAB

Effective: Recipient: Wheat

February 15, 2001

Institution: Monsanto Interstate destination: HI KS MO SD

Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APRIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official: Keyin tridle
signature: (b) (6), (b) (7)(C)
Date: 1/26/01
State: South Dakota Rotloc01/R4

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-016-26n (2001-77XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- $\mbox{M.}$ Brown, Missouri Dept of Agric., Jefferson City, \mbox{MO}
- K. Fridley, South Dakota Dept. of Agric., Pierre, SD
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA File number 01-016-26n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

991

מא ב

916367377085

038/038 00:08:28

-- xxxxxxxxx --



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Pebruary 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

pear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA





April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Re:	USDA#	Monsanto #
	01-017-12n	2001-144XRAB
	01-022-10n	2001-191XRAB
	01-022-11n	2001-192XRAB
	01-022-13n	2001-199XRAB
	01-022-15n	2001-201XRAB
	01-022-17n	2001-204XRAB
	01-022-18n	2001-206XRAB

Not a FOIA Deletion

Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (6), (b) (7)(C), (b) (4)

Sincerely yours,

(b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4)

> cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

December 19, 2003

MONSANTO COMPANY

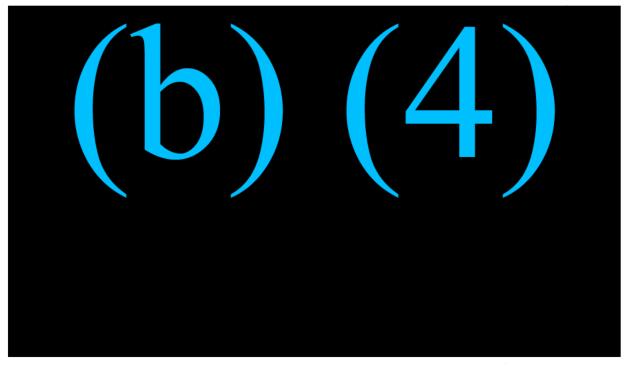
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Coly (1/27

Re: Our Letter of 4/16/01 concerning the following notifications:

1	<u>USDA#</u>		Monsanto #
	01-016-26n	* /	2001-77XRAB
/	01-017-12n	\	2001-144XRAB
	01-022-10n	1	2001-191XRAB
	01-022-11n	- 1	2001-192XRAB
	01-022-13n	- 1	2001-199XRAB
VI.	01-022-15n	1	2001-201XRAB
7	01-022-17n	/	2001-204XRAB
\	01-022-18n	/	2001-106XRAB

Dear Mr. Roman



Sincerely yours.
(b) (6), (b) (7)(C), (b) (4)

December 19, 2003

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

	2
<u>USDA#</u>	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

2001 Wheat Field Test Report USDA #01-016-26n Monsanto #2001-77XRAB

October 2, 2002

Biotech Field Compliance Team Monsanto Company

Location 2147306818

County

Codington County

State

SD

Codington County/SD (2147306818)

2001 Wheat Field Test Report USDA #01-016-26n Monsanto #2001-77XRAB

October 2, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

2147306818

Codington County

SD

Codington County/SD (2147306818)

Planting Date:

04/26/2001

Harvest Date:

08/24/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. ILS., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

OR120018 BR 007197

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

Bp number: 01-016-30n

2001-90XRAB Begin movement: 2/10/01 App number: Received: 1/16/01 End movement: 2/10/02 Institution: Monsanto Begin release: 2/10/01 Recipient: Wheat End release: 2/10/02 5.00 Status: Pending Acre: CBI status: CBI Effective date: 2/15/01 HT - Glyphosate tolerant Phenotype: Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip: Chesterfield, MO (b) (6), (b) (7)(C 636-737-7085 Telephone: [Assign Bp number and initial data entry [] Review by biotechnologist M Letter of notification to State -ed -ex [] State response O/d Loc Site Reg Interstate *Dest*HI * *WR * Interstate *Dest*KS * *SCR * Interstate *Dest*MO * *SCR * Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * *ND 1 Release 1*SCR * Enter genes into database Letter of acknowledgement/denial/withdraw [| Enter final data into database 7. [] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify

reason for tandiness: (KS) did not respond



Monsanto Reference ID

2001-90XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 11, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-30n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-90XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(

Phone

FAX

6), (b) (7)(C) monsanto.com

EMail

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

MO

February 10, 2001 - February 10, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto	Reference	ID
0004 001	DAD	

2001-90XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [

(b)(4)

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [(b)(4) (b)(4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-90XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN: DESTINATION: HI, KS, MO, ND HI, KS, MO, ND Ship From: н Honolulu *[County/Province, HI, (b)(4)U.S.A. CONTACT: b) (4), (b) (6), (b) (7)(C (b) (4), (b) (6), (b) (4), (b) (6), (b) (7)(0 KS Sedgwick County/Province, KS (b)(4)CONTACT: b) (4), (b) (6), (b) (7)(C)] - CBI MO *[U.S.A St. Louis County/Province, MO, (b)(4) CONTACT: MO,] - CBI ND (b)(4)Williams County/Province, ND, (b)(4) USA CONTACT ·^{(b) (6), (b)} USA (b) (4), (b) (6), (b) (7)(

Monsanto Reference ID

2001-90XRAB

Ship To:



Monsanto Reference ID

2001-90XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[Williams County/Province, ND, USA, 5 acres.

 $\begin{array}{c} \text{RESPONSIBLE PERSON/DESEADOUTD} \\ \text{(b) (4), (b) (6), (b) (7)(C)} \end{array} \\ \text{ND,} \\ \begin{array}{c} \text{(b) (4), (b) (6), (b) (6), (b) (7)(C)} \\ \text{DSA,} \\ \text{(b) (4), (b) (6), (b) (7)(C)} \end{array}$

] - CBI



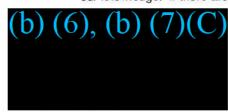
Monsanto Reference ID 2001-90XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 11, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-79XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-79XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-79XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Phone FAX

EMail

Monsanto Reference ID 2001-90XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-30n

1. USDA Reference Number

2. Applicant Reference Number 2001-90XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 10, 2001 - February 10, 2002

(b) (6), (b) (7)(C)

636/737-7085

(6), (b) (7)(C)@monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 11, 2001

Monsanto Reference ID

2001-90XRAB

designation of transformed line:

33391

Constructs: PV-TX

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-90XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens 8. Introduction Interstate Movement and Release Ship up to 3000 pounds of wheat seed to and from each location. **ORIGIN: DESTINATION:** HI, KS, MO, ND HI, KS, MO, ND Ship From: [CBI Deleted] -- *Honolulu County/Province, HI, U.S.A. KS CBI Deleted] -- *Sedgwick County/Province, KS, USA MO CBI Deleted] -- *St. Louis County/Province, MO, U.S.A ND CBI Deleted] -- *Williams County/Province, ND, USA Ship To:

HI

CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

Page 3 of 6

Monsanto Reference ID 2001-90XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

Monsanto Reference ID

2001-90XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Williams County/Province, ND, USA, 5 acres



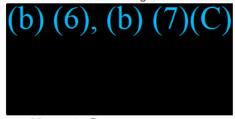
Monsanto Reference ID 2001-90XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 11, 2001



Phone

FAX

EMail

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.mensanto.com

January 11, 2001

Monsanto Reference ID 2001-90XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-30n

63198

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-90XRAB
- 3. Applicant/Responsible Party

b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

4. Duration of Introduction

Interstate Movement and Release

February 10, 2001 - February 10, 2002

(b) (6), (b) (7)(**C**

636/737-7085

b) (6), (b) (7)(C) monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

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designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI



Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

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GENE OF INTEREST

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Monsanto Reference ID

2001-90XRAB

Page 3 of 6

7. Mode of Transformati	on Disarmed Agrobacterium tumefaciens
8. Introduction	Interstate Movement and Release
Ship up to 3000 pound	s of wheat seed to and from each location.
ORIGIN:	DESTINATION:
HI, KS, MO, ND	HI, KS, MO, NE
Ship From:	
н	
[CBI Deleted] *	Honolulu County/Province, HI, U.S.A.
KS	
[CBI Deleted] *	Sedgwick County/Province, KS, USA
МО	
[CBI Deleted] *	St. Louis County/Province, MO, U S A
ND	
	Williams County/Province, ND, USA
Ship To:	
Simp Avi	

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

Monsanto Reference ID 2001-90XRAB

```
CBI Deleted ] -- *Sedgwick County/Province, KS, USA

MO

[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A

ND

[ CBI Deleted ] -- *Williams County/Province, ND, USA
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Color law law have been lown love had

Monsanto Reference ID

2001-90XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Williams County/Province, ND, USA, 5 acres

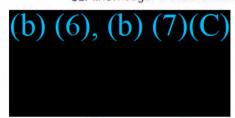


MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Monsanto Reference ID 2001-90XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 11, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-30n

Applicant #: 2001-90XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination:

Institution: Monsanto

NID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

	STATE RESPONSE TO NOTIFICATION
State conc	curs with APHIS determination.
State DOES	S NOT CONCUR and offers the following reasons:
Name of State off	ficial:
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-016-30n Applicant #: 2001-90XRAB

Received: January 16, 2001 Effective: February 15, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

79	
STATE F	RESPONSE TO NOTIFICATION
State concurs with APHIS	determination.
State DOES NOT CONCUR and	d offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-30n

Applicant #: 2001-90XRAB

Received: January 16, 2001 Effective: February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION State concurs with APHIS determination. State DOES NOT CONCUR and offers the following reasons: Name of State official: Signature: Date: State:____ Rptloc01/R4

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 17, 2001

Dear Mr. Nelson:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-30n

Applicant #: 2001-90XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE R	ESPONSE TO NOTIFICATION
State concurs with APHIS	determination.
State DOES NOT CONCUR and	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Ppt10c01/P4



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr .:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-30n

Applicant #: 2001-90XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

MD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

01650-028

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:

Name of State Okada

Signature:

Date: 15 February 2001

State:

Rptloc01/R4

FFR 1 6 2001



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eliqibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-30n

Applicant #: 2001-90XRAB

Received:

January 16, 2001

Effective:

February 15, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(6), (b) (7)(**(**

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION State concurs with APHIS determination. State DOES NOT CONCUR and offers the following reasons: 150m Name of State official: Signature: 31101 10 Date: WO State: Rptloc01/R4

PHS - Protecting American Agriculture

5 2001



Animal and Plant Health Inspection Service

4700 River Road Riverdals, MD 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 17, 2001_

Dear Mr. Nelson:

Enclosed is notification 01-016-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-016-30n

Applicant #: 2001-90xRAB

Received:

January 16, 2001

Effective: February 15, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-6910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

b) (6), (b) (

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE T	
State concurs with APHIS determina	tion.
State DOES NOT CONCUR and offers t	he following reasons:
Name of Starsofficial.	NELSON
Name of State official Act Act Signature: (b) (6), (b) (7)(C)	
Date: /- 28-0/	
State: ND	Rptloc01/R4

APMS - Protecting American Agricultura

An Equal Coportunity Employee

JAN 29 2001

NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

(b) (6), (b) (7)(C)

SENDER

DAVID R. NELSON State Entomologist (701) 328-4765 DIVISION PLANT PROTECTION

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N 01-016-30N

01-022-10N

1 'J 700 'ON

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota 600 E. Boulevard Ave. Dept. 602 Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPO

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker

USDA-APHIS-PPO

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- 1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
- 2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b) (7)(C)

CC

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release Notification no. 01-016-30n (2001-90XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

SI

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-016-30n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

001 OK

916367377085

038/038 00:08:28

- skokolok -



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b)

b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ. SCR, WR. Sacramento, CA



2001 Wheat Field Test Report USDA #01-016-30n Monsanto #2001-90XRAB

August 30, 2002

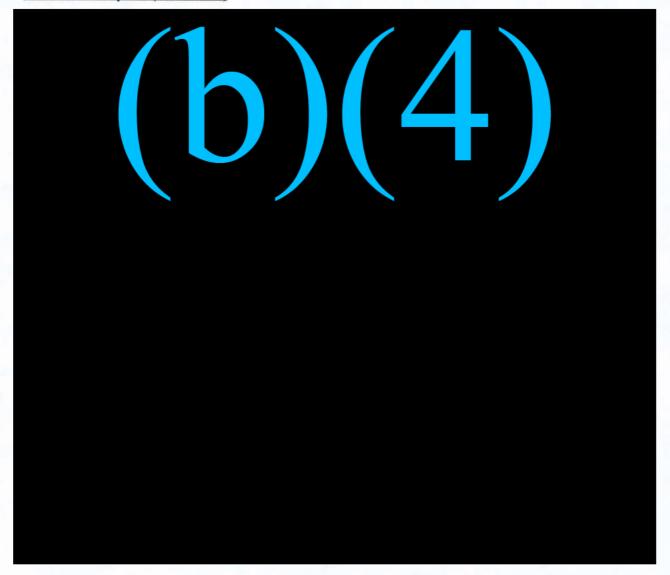
Biotech Field Compliance Team Monsanto Company

Location -896470389

CountyWilliams County

State ND

Williams County/ND (-896470389)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-016-30n Monsanto #2001-90XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

-896470389

Williams County

ND

Williams County/ND (-896470389)

Planting Date:

05/11/2001

Harvest Date:

08/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bp number: 01-017-01n

2001-64XRAB App number: Begin movement: 2/08/01 1/17/01 Received: End movement: 2/08/02 Institution: Monsanto Begin release: 2/08/01 Recipient: Wheat End release: 2/08/02 Status: Pending Acre: 5.00 Effective date: 2/16/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield, MO Telephone: (b) (6), (b) (7)(C) 636-737-7085 Fax: Initial [M/Assign Bp number and initial data entry 2. [] Review by biotechnologist [W Letter of notification to State Ted - CX 3. [] State response O/d Loc Site Reg Interstate *Dest*HI *WR * Interstate *Dest*KS *SCR * Interstate *Dest*MO * *SCR * Interstate *Dest*WA * *WR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*WA *WR * *WA Release 1*WR [] 5 . Enter genes into database Letter of acknowledgement/denial/withdraw Enter final data into database [] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify



Monsanto Reference ID

2001-64XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-01n

1. USDA Reference Number

2. Applicant Reference Number 2001-64XRAB

3. Applicant/Responsible Party

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 09, 2001

(b) (b), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI

Monsanto Reference ID 2001-64XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa//2 -- (b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST



Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-64XRAB

designation of transformed line: TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (
(b) (4)

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b) (4)

CBI

Monsanto Reference ID 2001-64XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- (b) (4)
(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI

Monsanto Reference ID 2001-64XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- (b) (4) (b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-64XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

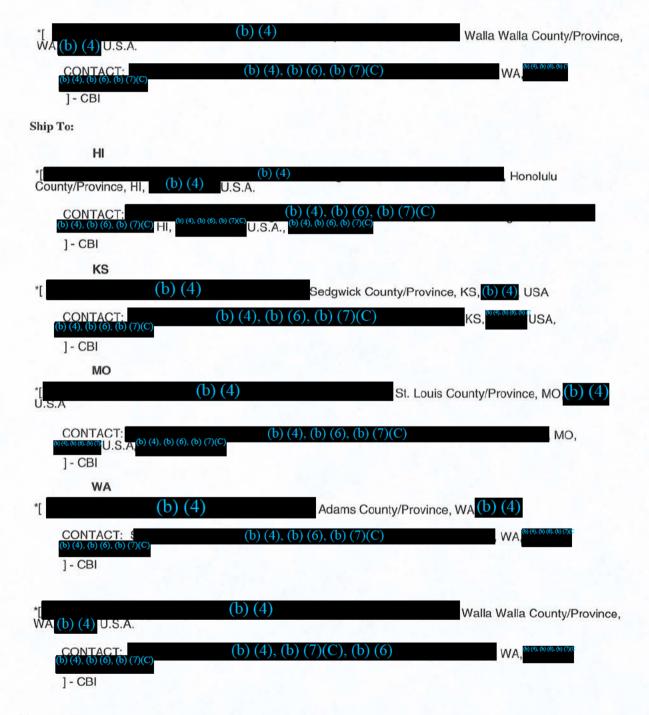
8. Introduction Interstate Movement and Release

Ship up to 4000 pound of whwat seed to and from each location.

ORIGIN: **DESTINATION:** HI, KS, MO, WA HI, KS, MO, WA Ship From: HI Honolulu County/Province, HI (b) (4) U.S.A. CONTACT: (b) (4), (b) (6), (b) (7)(C) HI, (0) (4), (0) (6), (0) (7)(C) U.S.A.,] - CBI KS Sedgwick County/Province, KS(b) (4) USA (b) (4) CONTACT: b) (4), (b) (6), (b) (7)(C (b) (4), (b) (6), (b) (7)(C)] - CBI MO St. Louis County/Province, MO.(b) (4) CONTACT: (b) (4), (b) (6), (b) (7)(C)] - CBI WA (b) (4)Adams County/Province, WA, (b) CONTACT: (b) (4), (b) (6), (b) (7)(C)] - CBI

Monsanto Reference ID

2001-64XRAB



Monsanto Reference ID 2001-64XRAB

Monsanto Reference ID 2001-64XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4) Walla Walla County/Province, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(7)

(b) (4), (b) (6), (b) (7)(C)

] - CBI



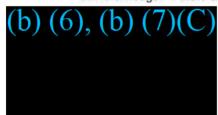
MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-64XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-64XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-64XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-64XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Phone

FAX

EMail

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 09, 2001

Monsanto Reference ID 2001-64XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-01n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-64XRAB
- 3. Applicant/Responsible Party

b) (6), (b) (7)(C

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)₂ monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

33391

Constructs: P

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted 1

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-64XRAB

7. Mode of Transformation			Disarmed Agrobacterium tumefaciens		
3. Introduction			Interstate Movement and Release		
Sh	nip up to 4000	pound of whwa	at seed to and from each lo	ocation.	
ORIGIN:				DESTINATIO	
HI, KS, MO, WA				HI, KS, M	O, WA
Ship	p From:				
	HI				
[CBI Deleted] *Honolulu County/Province, HI, U.S.A.					
[KS CBI Deleted] *Sedgwic	ck County/Province, KS, US	SA	
]	MO CBI Deleted] *St. Louis	s County/Province, MO, U.	S.A	
[WA CBI Deleted] *Adams (County/Province, WA		
[CBI Deleted] *Walla W	/alla County/Province, WA,	U.S.A.	

Page 6 of 9

Monsanto Reference ID 2001-64XRAB

```
HI

[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.

KS

[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA

MO

[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A

WA

[ CBI Deleted ] -- *Adams County/Province, WA

[ CBI Deleted ] -- *Walla Walla County/Province, WA, U.S.A.
```

Monsanto Reference ID

2001-64XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres



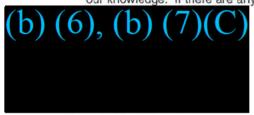
Monsanto Reference ID 2001-64XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 09, 2001



Phone FAX

EMail

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 09, 2001

Monsanto Reference ID 2001-64XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-01n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-64XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

b) (6), (b) (7)(C

636/737-7085

b) (6), (b) (7)(C)@ monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CELLETED

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

11

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator. NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Company of the last of the las

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs:

PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

CBI-DELENETED

Monsanto Reference ID 2001-64XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBINDELETED

Monsanto Reference ID

2001-64XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Company of the Compan

Monsanto Reference ID

2001-64XRAB

7. Mode of Transformat	ion Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release	
Ship up to 4000 pound	of whwat seed to and from each location.
ORIGIN:	DESTINATION:
HI, KS, MO, WA	HI, KS, MO, WA
Ship From:	
Ship From:	
	Honolulu County/Province, HI, U.S.A.
[Obliberated]	Tististad county/ Termos, this cleans
KS	
[CBI Deleted] '	*Sedgwick County/Province, KS, USA
MO	
[CBI Deleted]	*St. Louis County/Province, MO. U.S.A
WA	
	*Adams County/Province, WA
	9

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Page 6 of 9

CBINDELE TED

Monsanto Reference ID 2001-64XRAB

```
HI

CBI Deleted ] --- *Honolulu County/Province, HI, U.S.A.

KS
CBI Deleted ] --- *Sedgwick County/Province, KS, USA

MO
CBI Deleted ] --- *St. Louis County/Province, MO, U.S.A

WA
CBI Deleted ] --- *Adams County/Province, WA

CBI Deleted ] --- *Walla Walla County/Province, WA, U.S.A.
```


Monsanto Reference ID

2001-64XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres



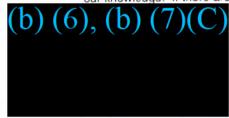
CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Monsanto Reference ID 2001-64XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 09, 2001

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-017-01n Applicant #: 2001-64XRAB

Received: January 17, 2001 Effective: February 16, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO WA

Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

	STATE RESPONSE TO NOTIFICATION
State concurs wi	th APHIS determination.
State DOES NOT C	ONCUR and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-01n

Applicant #: 2001-64XRAB

Received:

January 17, 2001

Effective:

Recipient:

February 16, 2001

Institution: Monsanto

Wheat

Interstate destination: HI KS MO WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RES	SPONSE TO NOTIFICATION
State concurs with APHIS de	etermination.
State DOES NOT CONCUR and c	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-01n

Applicant #: 2001-64XRAB

Received:

January 17, 2001

Effective: February 16, 2001

Recipient:

Wheat

Institution: Monsanto
Interstate destination: HI KS MO WA

AM OM S

Release destination:

7.77

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
s	State concurs with APHIS determination.
s	State DOES NOT CONCUR and offers the following reasons
Name of	State official:
Signatur	re:
Date:	
State:	Rptloc01/R4

Mr. Thomas L. Wessels, Plant Services Program Manager Laboratory Services Division Washington Department of Agriculture 1111 Washington Street Olympia, WA 98504-2560 Dear Mr. Wessels:

January 17, 2001

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-017-01n Applicant #: 2001-64XRAB

Received: January 17, 2001 Effective: February 16, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RES	SPONSE TO NOTIFICATION
State concurs with APHIS de	etermination.
State DOES NOT CONCUR and c	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rpt1oc01/R4



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 JAN 2 5 2001 01980 - 039

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number Received:

01-017-01n

January 17, 2001

Effective:

Applicant #: 2001-64XRAB

Institution: Monsanto

Recipient:

February 16, 2001

Interstate destination: HI KS MO WA

Release destination: WA

wA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Carol L. Okada

Signature:

(b) (6), (b) (7)(C)

Date: 15 February 2001

State:

Hawaii

Post-it® Fax Note 7671 Date # of pages ►

To M. Jackson From C. Okada.

Co./Dept. Co.

Phone # Phone #

Fax # Fax #



APTHS - Protecting American Agriculture

OR120018 BR 007275

FEB 1 6 2001



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-01m

Applicant #: 2001-64XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STA	ATE RESPONSE TO NOTIFICATION
State concurs with A	PHIS determination.
State DOES NOT CONCUR	and offers the following reasons:
Name of State official:	16 chard E Brown
signature:_ (b) (6)	(a, (b) (7)(C)
Date: 2/2/0)	
State: mo	Rptloc01/R4





Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager - January 17, 2001 Laboratory Services Division Washington Department of Agriculture 1111 Washington Street Olympia, WA 98504-2560

Dear Mr. Wessels:

Enclosed is notification 01-017-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-01n

Applicant #: 2001-64XRAB

Received:

January 17, 2001

Effective: February 16, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

ce: K. Stoaks, PPO, Sacramento C	CC:	Stoaks, PPQ, Sacramen	to C	Z
----------------------------------	-----	-----------------------	------	---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: MARINAS

Signature: (b) (6), (b) (7) (C)

Date: 2 / 6/

State: WA

APHS - Prozecung American Agriculture

FEB 2 2001

Rptloc01/R4

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear

(b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-017-01n (2001-64XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

15

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Ouarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- T. Wessels, Washington Dept. of Agric., Olympia, WA
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA File number 01-017-01n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO. =497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

991 OK

916367377085

038/038 00:08:28

- ****** -



Animat and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 53198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Motification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Flant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA



March 23, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

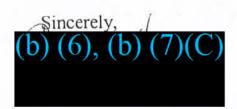
Ms. Dianne Hatmaker Animal and Plant Health Inspection Services Biotechnology and Scientific Services 4700 River Road, Unit 147 Riverdale, MD

Dear Ms. Hatmaker;

In reviewing several acknowledged wheat notification, a typing error was discovered in line numbers. The line numbers should be TA_S0317, TA_S0635, TA_01081, TA_S2520, TA_S5450, TA_9240, TA_S0719, TA_S7535, TA_S7890, TA_S9512, TA_S10430. These lines were submitted with a hyphen rather than an underscore. The affected notifications were

Monsanto #	USDA#
2001-65XRAB	01-017-02n
2001-74XRAB	01-016-25n
2001-64XRAB	01-017-01n
2001-144XRAB	01-017-12n
2001-201XRAB	01-022-15n

If you have any additional questions, please call me my telephone number is (b) (6), (b) (7)(C)



cc: M. Isherwood Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric. Topeka, Ks

M. Brown, Missouri Dept of Agric. Jefferson City, MO

- J. Griesbach, Oregon Dept. of Agric., Salem, Oregon
- T. Wessels, Washington Dept. of Agric., Olympia, WA
- R. Stokes, PPQ, WR, SCR, Sacramento, CA
- L. Witham, Montana Dept. of Agric., Helena, WA
- D. Nelson, North Dakota Dept. of Agric., Bismarch, ND
- K. Fridley, South Dakota Dept. of Agric., Pierre, SD

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

2001 Wheat Field Test Report USDA #01-017-01n Monsanto #2001-64XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

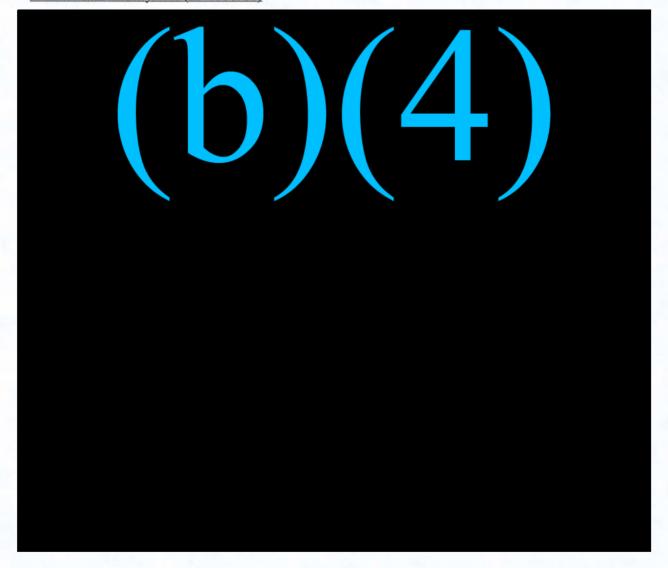
Location 2147306760

County

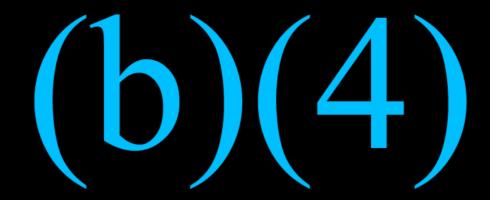
Walla Walla County

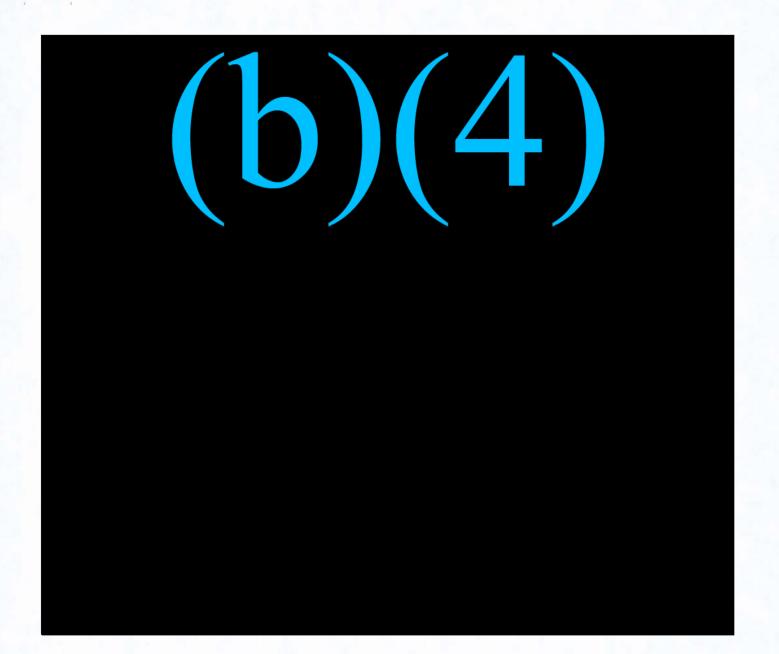
State WA

Walla Walla County/WA (2147306760)









CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report USDA #01-017-01n Monsanto #2001-64XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

2147306760

Walla Walla County

WA

Walla Walla County/WA (2147306760)

Planting Date:

03/21/2001

Harvest Date:

07/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date:

03/21/2001

Harvest Date:

07/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 03/21/2001

Harvest Date: 07/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 03/23/2001

Destruct Date: 06/26/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/10/2001

Harvest Date: 07/26/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bp number: 01-017-02n

App number: 2001-65XRAB Begin movement: 2/08/01 Received: 1/17/01 End movement: 2/08/02 Institution: Monsanto Begin release: 2/08/01 Recipient: Wheat End release: 2/08/02 Status: Pending Acre: 10.00 Effective date: 2/16/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip: Chesterfield, MO (b) (6), (b) (7)(C 636-737-7085 Fax: Initial Assign Bp number and initial data entry [Review by biotechnologist JAN 18 2001 [Y Letter of notification to State Fed - ex 3. [] State response O/d Loc Site Reg Interstate *Dest*HI *WR * Interstate *Dest*KS *SCR * Interstate *Dest*MO * *SCR * Interstate *Dest*OR Interstate *Dest*WA *WR Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*OR *WR Interstate *Orig*WA *WR Release *OR 1*WR [1 [1 Enter genes into database Letter of acknowledgement/denial/withdraw [K&N] [2/26/01] Enter final data into database 7 -[] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify Mason for tandiness: (KS) did not respond



Phone FAX

EMail

Monsanto Reference ID 2001-65XRAB

....

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-65XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

636/737-7085

(6), (b) (7)(C)@monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 09, 2001

Page 1 of 10

CBI

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

(b)(4)Promoter: CMoVa/l2 --

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST



Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- I (b)(4) (CBI) (b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b)(4)

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_\$7535, TA_\$7890, TA_\$9512, TA_\$10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-65XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

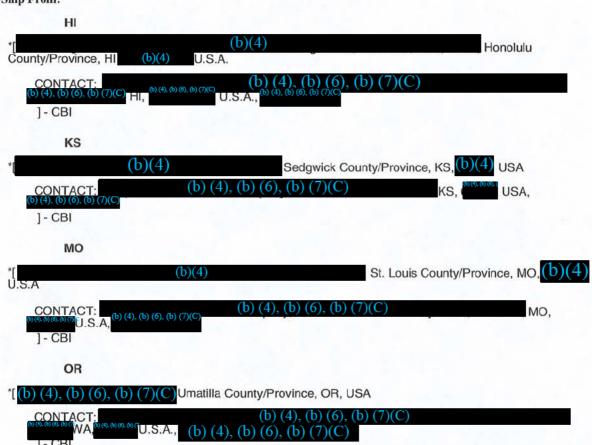
Interstate Movement and Release

Ship up to 4000 pounds of wheat seet to and from each location.

ORIGIN:
HI, KS, MO, OR, WA
Ship From:

DESTINATION:

HI, KS, MO, OR, WA



Monsanto Reference ID 2001-65XRAB



Monsanto Reference ID 2001-65XRAB

CONFIDENTIAL

Monsanto Reference ID

2001-65XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

(b) (4), (b) (6), (b) (7)(C) Umatilla County/Province, OR, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) WA, (b) (6), (b) (7)(C)

] - CBI



CONFIDENTIAL

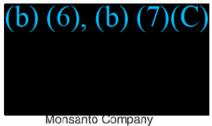
Monsanto Reference ID 2001-65XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



January 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-65XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-65XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-65XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Phone FAX

EMail

Monsanto Reference ID 2001-65XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-65XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)@monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

НТ

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 09, 2001

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9512, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-65XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seet to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, OR, WA

HI, KS, MO, OR, WA

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Page 6 of 9

Monsanto Reference ID 2001-65XRAB

HI

[CBI Deleted] --- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] --- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] --- *St. Louis County/Province, MO, U.S.A

OR

[CBI Deleted] --- *Umatilla County/Province, OR, USA

WA

[CBI Deleted] --- *Walla Walla County/Province, WA, U.S.A.

Monsanto Reference ID

2001-65XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

[CBI Deleted] -- Umatilla County/Province, OR, USA, 10 acres



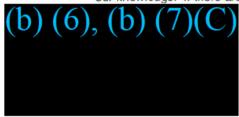
Monsanto Reference ID 2001-65XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 09, 2001



Phone FAX

EMail

Monsanto Reference ID 2001-65XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-65XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

(b) (6), (b) (7)(C

636/737-7085

b) (6), (b) (7)(C)@monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELERIED

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CB!

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

11

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CEILDEN LE TEND

Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_S2520, TA_S5450,

Constructs:

PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

CEILD For La For The D

Monsanto Reference ID 2001-65XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

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Monsanto Reference ID

2001-65XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9512, TA_S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



Monsanto Reference ID

2001-65XRAB

 Mode	-47		Same.	adiam
	α	rans	111111111111111111111111111111111111111	anion

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seet to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, OR, WA

HI, KS, MO, OR, WA

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO. U.S.A

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Page 6 of 9



Monsanto Reference ID 2001-65XRAB

HI
[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS
[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO
[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

OR
[CBI Deleted] -- *Umatilla County/Province, OR, USA

WA
[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A

Charles Land Land Then Do

Monsanto Reference ID

2001-65XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

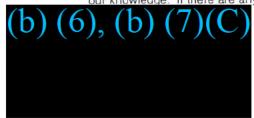
CBI Deleted] -- Umatilla County/Province, OR, USA, 10 acres



Monsanto Reference ID 2001-65XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 09, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-017-02n Applicant #: 2001-65XRAB

Received: January 17, 2001 Effective: February 16, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO OR WA

Release destination: OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE	E TO NOTIFICATION	
State concurs with APHIS determi	ination.	
State DOES NOT CONCUR and offers	s the following reasons:	
Name of State official:		
Signature:		
Date:		
State:	Rptloc01/R4	

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective: February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO OR WA

Release destination:

OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
State c	concurs with APHIS determination.
State D	OES NOT CONCUR and offers the following reasons:
Name of State	official:
Signature:	
Date:	
State:	Ppt1oc01/P4

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO OR WA

Release destination:

OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE	RESPONSE TO NOTIFICATION
State concurs with APHI	S determination.
State DOES NOT CONCUR a	and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Ppt10001/P4

Mr. John Griesbach Oregon Department of Agriculture Plant Division 635 Capitol St., N.E. Salem, OR 97310-0110 January 17, 2001

Dear Mr. Griesbach:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-017-02n Applicant #: 2001-65XRAB

Received: January 17, 2001 Effective: February 16, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO OR WA

Release destination: OF

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION _____State concurs with APHIS determination. ____State DOES NOT CONCUR and offers the following reasons: Name of State official:_____ Signature:_____ Date:_____ State:_____ Rptloc01/R4

Mr. Thomas L. Wessels, Plant Services Program Manager Laboratory Services Division Washington Department of Agriculture 1111 Washington Street Olympia, WA 98504-2560

January 17, 2001

Dear Mr. Wessels:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective: February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO OR WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE	E RESPONSE TO NOTIFICATION
State concurs with APHI	S determination.
State DOES NOT CONCUR a	and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO OR WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:

Name of State official

Okada

Date: 15 February 2001

State:_

Hawai

Rptloc01/R4



FEB 1 6 2001



Animal and Plant Health inspection Service

4700 River Road Rivergale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO OR WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION State concurs with APHIS determination. State DOES NOT CONCUR and the following reasons: Name of State official 01 (31 01 WD State: Rptloc01/R4



An Equal Opportunity Employee OR120018_BR_007331

Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. John Griesbach Oregon Department of Agriculture Plant Division 635 Capitol St., N.E. Salem, OR 97310-0110

January 17, 2001

Dear Mr. Griesbach:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO OR WA

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

RECEIVED

JAN 24 2001 AGRICULTURE PLANT DIVISION

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

1	STATE RESPONSE TO NOTIFICATION	1
State	concurs with APHIS determination. * see attached let	Ter,
State	DOES NOT CONCUR and offers the following reasons:	
Name of State	official: Danie J. Hilburn	
Signature:_	(b) (6), (b) (7)(C)	
Date: 2/1	4/01	
State: Of	PG D P Rptloc01/R4	





Department of Agriculture

635 Capitol Street NE Salem, OR 97301-2532

February 14, 2001

Mary Jackson Biotechnology Program Operations Permits and Risk Assessments USDA, APHIS, PPQ 4700 River Road Riverdale, MD 20737



Dear Ms. Jackson:

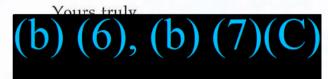
We have received and reviewed notification numbers 01-016-22n and 01-017-02n. These notifications were submitted by Monsanto for Glyphosate tolerant wheat. Due to an extremely sensitive market situation at the current time, we'd like to see stringent safeguards applied before this research proceeds in Oregon in 2001. We also suggest that given the current market climate around the world, USDA carefully review national requirements for research on genetically modified wheat. In particular, isolation distances designed to prevent mechanical mixing do not address pollen transfer concerns. Until tolerances for genetically modified wheat are established and accepted, protocols should reflect the need to ensure conventional wheat crops are completely free of contamination by genetically modified wheat.

Most of Oregon's wheat is grown for export and much of it goes to Japan. Since Japan will require mandatory labeling of genetically modified commodities in April of this year, it is extremely important that we ensure genetically modified wheat is fully segregated from Oregon's conventional commercial wheat crop. Inadvertent contamination of the conventional wheat crop would seriously constrain wheat grower's access to Japanese and other export markets. We suggest the following modifications to existing requirements to ensure that this 2001 research is done with the utmost concern for market preservation:

- 1.) Total acreage of plots is limited to 1.5 acres.
- 2.) Plots of genetically modified wheat must be separated from all other spring wheat by a distance of at least 660 ft.
- 3.) Plots of genetically modified wheat must be separated from non-spring wheat by a distance of at least 90 ft.
- 4.) Goatgrass (*Aegilops* sp.) must be eliminated from the area around the plots for a distance of at least 660 ft.
- 5.) Equipment used to plant and harvest the genetically modified wheat must be completely cleaned of all seeds and other plant parts on site before reuse.

- 6.) All parts of the genetically modified plants, including the seeds, must be destroyed on site. The plants must be sprayed with a labeled herbicide before plowing, flailing or other mechanical destruction.
- 7.) Plots must not be replanted into wheat in the year following planting of the genetically modified crop and the plots must be monitored for any volunteers. Volunteers must be destroyed.
- 8.) Either USDA must inspect the plots for isolation distance compliance and monitor the crop destruction process or the Oregon Department of Agriculture must be supplied with the information necessary to permit monitoring by ODA.

Thank you for helping us to make sure that this research does not interfere with the orderly marketing of Oregon's wheat crop. If you have any questions please don't hesitate to contact me.



Daniel J. Hilburn Administrator, Plant Division (503) 986-4663

cc: (b) (6), (b) (7)(C)Monsanto



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager Laboratory Services Division Washington Department of Agriculture 1111 Washington Street Olympia, WA 98504-2560 January 17, 2001

Dear Mr. Wassels:

Enclosed is notification 01-017-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-02n

Applicant #: 2001-65XRAB

Received:

January 17, 2001

Effective: I

February 16, 2001

Institution: Monsanto

Recipient: Wheat

Wheat

Interstate destination: HI KS MO OR WA

Release destination:

OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b)(6),(b)(7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosura

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESI	PONSE TO NOTIFICATION
State concurs with APHIS det	termination.
State DOES NOT CONCURpand of	fers the following reasons:
Name of State official: That Man	all Mussin
(b)(6),(b)	(7)(C)
Date: 2/1/01	
State: WA	PDF10G01/P4

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release
Notification no. 01-017-02n (2001-65XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Oregon, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Oregon has (attached) conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

15/

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC.

- M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
- T. Sim, Kansas State Board of Agric., Topeka, KS
- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- J. Griesbach, Oregon Dept. of Agric., Salem, OR
- T. Wessels, Washington Dept. of Agric., Olympia, WA
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-017-02n



Department of Agriculture 635 Capitol Street NE Salem, OR 97301-2532

Sale



February 14, 2001

Mary Jackson
Biotechnology Program Operations
Permits and Risk Assessments
USDA, APHIS, PPQ
4700 River Road
Riverdale, MD 20737

Dear Ms. Jackson:

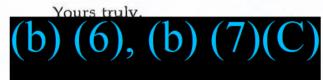
We have received and reviewed notification numbers 01-016-22n and 01-017-02n. These notifications were submitted by Monsanto for Glyphosate tolerant wheat. Due to an extremely sensitive market situation at the current time, we'd like to see stringent safeguards applied before this research proceeds in Oregon in 2001. We also suggest that given the current market climate around the world, USDA carefully review national requirements for research on genetically modified wheat. In particular, isolation distances designed to prevent mechanical mixing do not address pollen transfer concerns. Until tolerances for genetically modified wheat are established and accepted, protocols should reflect the need to ensure conventional wheat crops are completely free of contamination by genetically modified wheat.

Most of Oregon's wheat is grown for export and much of it goes to Japan. Since Japan will require mandatory labeling of genetically modified commodities in April of this year, it is extremely important that we ensure genetically modified wheat is fully segregated from Oregon's conventional commercial wheat crop. Inadvertent contamination of the conventional wheat crop would seriously constrain wheat grower's access to Japanese and other export markets. We suggest the following modifications to existing requirements to ensure that this 2001 research is done with the utmost concern for market preservation:

- 1.) Total acreage of plots is limited to 1.5 acres.
- 2.) Plots of genetically modified wheat must be separated from all other spring wheat by a distance of at least 660 ft.
- 3.) Plots of genetically modified wheat must be separated from non-spring wheat by a distance of at least 90 ft.
- 4.) Goatgrass (Aegilops sp.) must be eliminated from the area around the plots for a distance of at least 660 ft.
- 5.) Equipment used to plant and harvest the genetically modified wheat must be completely cleaned of all seeds and other plant parts on site before reuse.

- 6.) All parts of the genetically modified plants, including the seeds, must be destroyed on site. The plants must be sprayed with a labeled herbicide before plowing, flailing or other mechanical destruction.
- 7.) Plots must not be replanted into wheat in the year following planting of the genetically modified crop and the plots must be monitored for any volunteers. Volunteers must be destroyed.
- 8.) Either USDA must inspect the plots for isolation distance compliance and monitor the crop destruction process or the Oregon Department of Agriculture must be supplied with the information necessary to permit monitoring by ODA.

Thank you for helping us to make sure that this research does not interfere with the orderly marketing of Oregon's wheat crop. If you have any questions please don't hesitate to contact me.



Daniel J. Hilburn Administrator, Plant Division (503) 986-4663

(b) (6), (b) (7)(C)

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

ABBR NO. STN NO. COMM.

STATION NAME/TEL NO.

PAGES DURATION

001

OK

916367377085

P38/P38 PD: 08: 28

- xxxxxxx -

kokolololokok



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12m (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia. WA R. Stoaks, PPQ. SCR, WR, Sacramento, CA





March 23, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

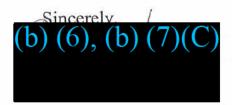
Ms. Dianne Hatmaker Animal and Plant Health Inspection Services Biotechnology and Scientific Services 4700 River Road, Unit 147 Riverdale, MD

Dear Ms. Hatmaker;

In reviewing several acknowledged wheat notification, a typing error was discovered in line numbers. The line numbers should be TA_S0317, TA_S0635, TA_01081, TA_S2520, TA_S5450, TA_9240, TA_S0719, TA_S7535, TA_S7890, TA_S9512, TA_S10430. These lines were submitted with a hyphen rather than an underscore. The affected notifications were

Monsanto #	USDA#		
2001-65XRAB	01-017-02n		
2001-74XRAB	01-016-25n		
2001-64XRAB	01-017-01n		
2001-144XRAB	01-017-12n		
2001-201XRAB	01-022-15n		

If you have any additional questions, please call me my telephone number is (b) (6), (b) (7)(C)



cc: M. Isherwood Hawaii Dept. of Agric., Honolulu, HI

T. Sim, Kansas State Board of Agric. Topeka, Ks

M. Brown, Missouri Dept of Agric. Jefferson City, MO



- J. Griesbach, Oregon Dept. of Agric., Salem, Oregon
- T. Wessels, Washington Dept. of Agric., Olympia, WA
- R. Stokes, PPQ, WR, SCR, Sacramento, CA
- L. Witham, Montana Dept. of Agric., Helena, WA
- D. Nelson, North Dakota Dept. of Agric., Bismarch, ND
- K. Fridley, South Dakota Dept. of Agric., Pierre, SD

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com Bp number: 01-017-12n

App number: 2001-144XRAB Begin movement: 2/14/01 Received: 1/17/01 End movement: 2/14/02 Institution: Monsanto Begin release: 2/14/01 Recipient: Wheat End release: 2/14/02 Status: Pending Acre: 15.00 Effective date: 2/16/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip: Chesterfield, MO Telephone: 636-737-7085 Initial Assign Bp number and initial data entry Review by biotechnologist M Letter of notification to State Fed - ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * [1 Interstate *Dest*MO *SCR * Γ] Interstate *Dest*SD *SCR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*SD *SCR * Release 3*SCR * [] Enter genes into database /Letter of/acknowledgement/denial/withdraw Enter final data into database [2/26/01] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker,

Reason for tardiness (KS) did not respond

Does not qualify

Acronding 120



Monsanto Reference ID

2001-144XRAB

Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 15, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-12n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-144XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

b) (6), (b) (7)(C)@monsanto.com

FAX

636/737-7085

EMail

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2001 - February 14, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

нт

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

33391

Constructs:

CP4.

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(h)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/i5 -- i (b)(4) (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs:

PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [(b)(4)

(b)(4)

CBI

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [

Page 3 of 10

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --- i

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- (b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-144XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4,000 pounds of wheat seed to and from each location.

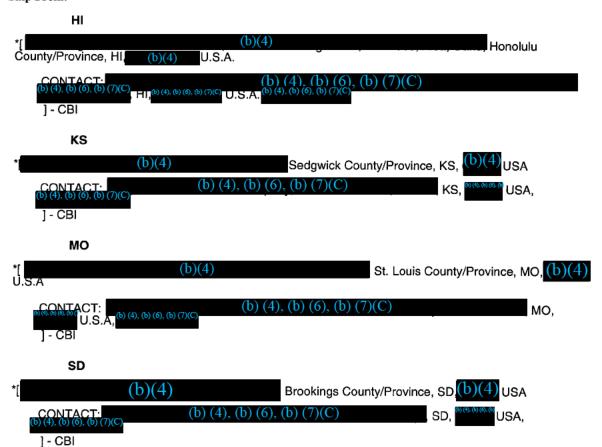
ORIGIN:

DESTINATION:

HI, KS, MO, SD

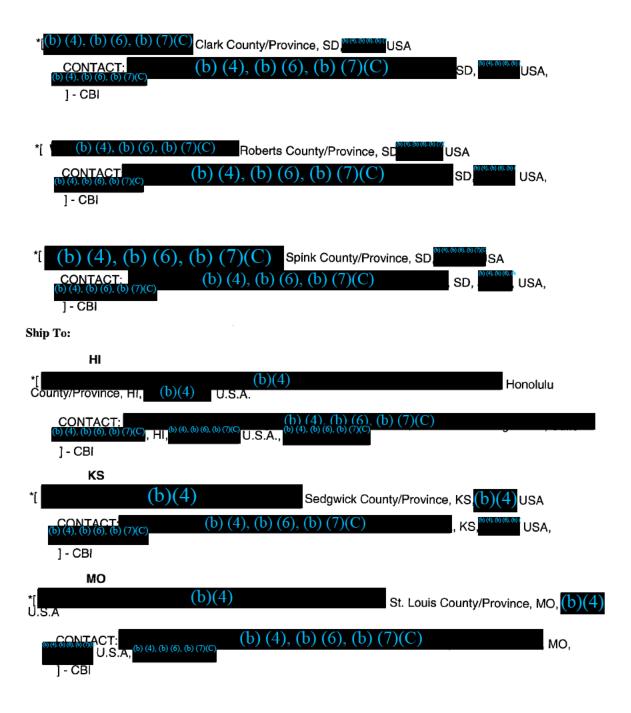
HI, KS, MO, SD

Ship From:



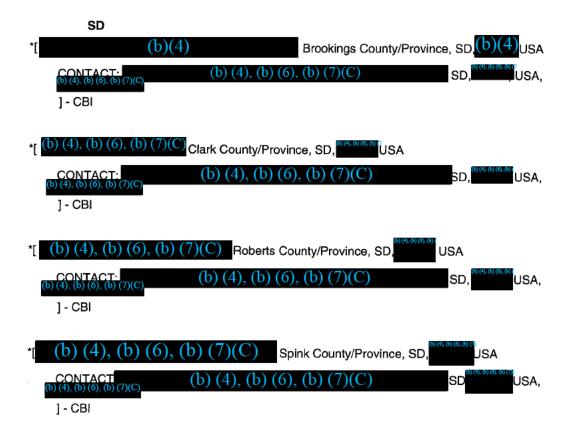
Page 6 of 10

Monsanto Reference ID 2001-144XRAB



Monsanto Reference ID

2001-144XRAB



Monsanto Reference ID

2001-144XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (3)

SD

[(b) (4), (b) (6), (b) (7)(C) Clark County/Province, SD, USA, 5 acres.

] - CBI

(b) (4), (b) (6), (b) (7)(C) Roberts County/Province, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER USA,

] - CBI

(b) (4), (b) (6), (b) (7)(C) Spink County/Province, SD, USA, 5 acres.

(b) (4),

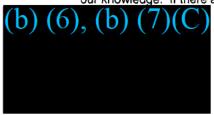
] - CBI



Monsanto Reference ID 2001-144XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 15, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-79XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-79XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-79XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID

2001-144XRAB

Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 15, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-12n

63198

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-144XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

Phone

FAX

EMail

(b) (6), (b) (7)(C

636/737-7085 (b) (6) (b) (7

monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 14, 2001 - February 14, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

33391

Constructs: P\

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-144XRAB

7. Mode of Transformation			ormation	Disarmed Agrobacterium tumefaciens			
8.	8. Introduction			Interstate Movement and Release			
	SI	nip up to 4,000	pounds of wheat	seed to and from each	location.		
	ORIGIN:				HI, KS,		_
	H	ii, KS, MO, S	3D		пі, ко,	MO, SI	-
	Shij	p From:					
		н					
	[CBI Deleted] *Honolulu Co	unty/Province, HI, U.S.	Α.		
		KS					
	[CBI Deleted] *Sedgwick Co	ounty/Province, KS, US	SA		
		МО					
	[CBI Deleted] *St. Louis Co	unty/Province, MO, U.S	S.A		
		SD					
	[] *Brookings C	ounty/Province, SD, US	6A		
	-						
	[CBI Deleted	1 *Clark County	//Province, SD, USA			
	L	JD. DOIOIOU	, Clark County				

Page 6 of 10

Monsanto Reference ID 2001-144XRAB

```
[ CBI Deleted ] -- *Roberts County/Province, SD, USA
 [ CBI Deleted ] -- *Spink County/Province, SD, USA
Ship To:
          ΗΙ
 [ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          МО
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          SD
[ CBI Deleted ] -- *Brookings County/Province, SD, USA
```

Monsanto Reference ID

2001-144XRAB

- [CBI Deleted] -- *Clark County/Province, SD, USA
- [CBI Deleted] -- *Roberts County/Province, SD, USA
- [CBI Deleted] -- *Spink County/Province, SD, USA

Monsanto Reference ID

2001-144XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (3)

SD

[CBI Deleted] -- Clark County/Province, SD, USA, 5 acres

[CBI Deleted] -- Roberts County/Province, SD, USA, 5 acres

[CBI Deleted] -- Spink County/Province, SD, USA, 5 acres

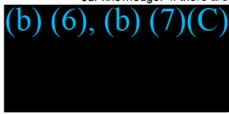


Monsanto Company 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-144XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 15, 2001



Monsanto Reference ID

2001-144XRAB

Monsanto Company
700 Chesterfield Pkwy North
Chesterfield, Missouri 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 15, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-12n

63198

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-144XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX EMail 636/737-7085 (6) (b) (7)

(6), (b) (7)(C)₃ monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

4. Duration of Introduction

Interstate Movement and Release

February 14, 2001 - February 14, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

нт

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

33391

Constructs: PV-

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 - 1 (b)(4)

СВІ

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [(b)(4) (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

And the second of the second o

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [(b)(4) CBI (b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3'-- (b)(4)



Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Page 4 of 10



Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Page 5 of 10

CONFIDENTIAL

Monsanto Reference ID

2001-144XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4,000 pounds of wheat seed to and from each location.

ORIGIN:

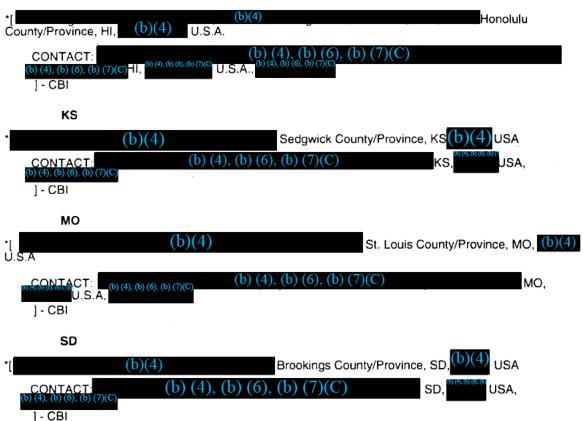
DESTINATION:

HI, KS, MO, SD

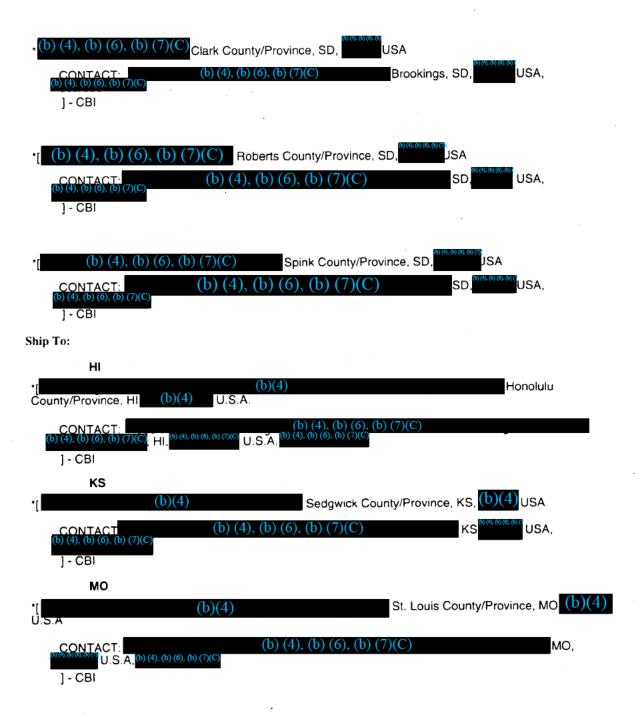
HI, KS, MO, SD

Ship From:

н



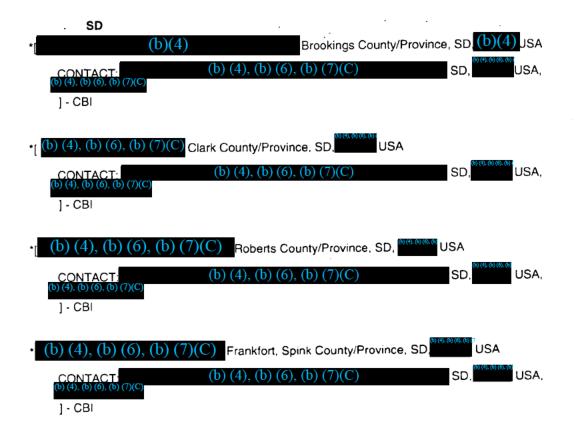
Monsanto Reference ID 2001-144XRAB



Page 7 of 10



2001-144XRAB



2001-144XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (3)

SD

(b) (4), (b) (6), (b) (7)(C) Clark County/Province, SD, USA, 5 acres.

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Roberts County/Province, SD, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Spink County/Province, SD, USA, 5 acres.

BESPONSIBLE PERSON/RESEARCHER: SD 94.00.00 JSA, (0.4), (0.6), (0.70)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

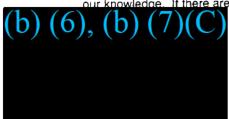


CONFIDENTIAL

Monsanto Reference ID 2001-144XRAB Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 15, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-79XRAB Page 2

Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility,

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification Notification 2001-79XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-79XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

CBI-DELETED

Phone FAX

EMail

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 15, 2001

Monsanto Reference ID

2001-144XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-017-12n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-144XRAB
- 3. Applicant/Responsible Party

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 14, 2001 - February 14, 2002

b) (6), (b) (7)(C)@monsanto.com

5. Recipient

Wheat, Triticum aestivum-

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite



RЛ	۸n	62	nto	Ra	for	·an	0	ID
IVI	UII	Sa	HU	ne	161	e i	LE	ı

2001-144XRAB

designation of transformed line:

33391

Constructs: PV-T

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted -]-----

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Age to the second of the secon

Monsanto Reference ID

2001-144XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]



2001-144XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



2001-144XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

2001-144XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4,000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, SD

HI, KS, MO, SD

Ship From:

Н

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI Deleted] -- *Clark County/Province, SD, USA

Page 6 of 10



Monsanto Reference ID 2001-144XRAB

```
[ CBI Deleted ] -- *Roberts County/Province, SD, USA
 [ CBI Deleted ] -- *Spink County/Province, SD, USA
Ship To:
          HI
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
   CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
   CBI Deleted ] -- *St. Louis County/Province, MO. U.S.A
          SD
  CBI Deleted ] -- *Brookings County/Province, SD, USA
```



Monsanto Reference ID 2001-144XRAB

- [CBI Deleted] -- *Clark County/Province, SD, USA
- [CBI Deleted] -- *Roberts County/Province, SD, USA
- [CBI Deleted] -- *Spink County/Province, SD, USA

2001-144XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (3)

SD

[CBI Deleted] -- Clark County/Province, SD, USA, 5 acres

[CBI Deleted] -- Roberts County/Province, SD, USA, 5 acres

[CBI Deleted] -- Spink County/Province, SD, USA, 5 acres



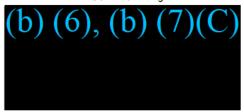
CBI-DELETED

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-144XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 15, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective: February 16, 2001

Recipient:

Institution: Monsanto

Wheat

Interstate destination: HI KS MO SD

Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NO	TIFICATION
State concurs with APHIS determination	
State DOES NOT CONCUR and offers the fo	
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective: February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONS	E TO NOTIFICATION
State concurs with APHIS determ	ination.
State DOES NOT CONCUR and offer	s the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION	
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following reason	s:
Name of State official:	
Signature:	
Date:	
State:Rptloc01/R4	

Mr. Kevin Fridley Division of Agricultural Services South Dakota Department of Agriculture Foss Building-523 East Capitol Pierre, SD 57501-3182

January 17, 2001

Dear Mr. Fridley:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONS	SE TO NOTIFICATION
State concurs with APHIS determ	mination.
State DOES NOT CONCUR and offer	es the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rotloc01/R4



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:

Name of State offi Signature:

Date: 15 February 2001

State:

Rptloc01/R4





Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO SD

Release destination:

SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State officials Michael & Bown
Name of State officials 11046 6 5000
signature: (b) (6), (b) (7)(C)
Date: 01(25/0)
State: Rptloc01/R4

JAM 30 2001



Animat and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Kevin Fridley Division of Agricultural Services South Dakota Department of Agriculture Foss Building-523 East Capitol Pierre, SD 57501-3182

January 17, 2001

Dear Mr. Fridley:

Enclosed is notification 01-017-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bo number

01-017-12n

Applicant #: 2001-144XRAB

Received:

January 17, 2001

Effective:

February 16, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO SD

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Ouarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

State: South

Rptloc01/R4 .



APTES - Protesting American Agricultura

An Equal Opportunity Employee

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b)(6),(b)(7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-017-12n (2001-144XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|5|

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI

T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- K. Fridley, South Dakota Dept. of Agric., Pierre, SD
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA
- File number 01-017-12n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

901

UK S

916367377085

238/038 00:08:28

- skolokokok -

- *****



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear(b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia. WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA



March 23, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085 . .
http://www.monsanto.com

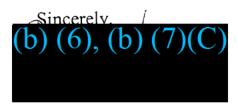
Ms. Dianne Hatmaker Animal and Plant Health Inspection Services Biotechnology and Scientific Services 4700 River Road, Unit 147 Riverdale, MD

Dear Ms. Hatmaker;

In reviewing several acknowledged wheat notification, a typing error was discovered in line numbers. The line numbers should be TA_S0317, TA_S0635, TA_01081, TA_S2520, TA_S5450, TA_9240, TA_S0719, TA_S7535, TA_S7890, TA_S9512, TA_S10430. These lines were submitted with a hyphen rather than an underscore. The affected notifications were

Monsanto #	USDA#
2001-65XRAB	01-017-02n
2001-74XRAB	01-016-25n
2001-64XRAB	01-017-01n
2001-144XRAB	01-017-12n
2001-201XRAB	01-022-15n

If you have any additional questions, please call me my telephone number is (b) (6), (b) (7) (C)



cc: M. Isherwood Hawaii Dept. of Agric., Honolulu, HI

T. Sim, Kansas State Board of Agric. Topeka, Ks

M. Brown, Missouri Dept of Agric. Jefferson City, MO

- J. Griesbach, Oregon Dept. of Agric., Salem, Oregon
- T. Wessels, Washington Dept. of Agric., Olympia, WA
- R. Stokes, PPQ, WR, SCR, Sacramento, CA
- L. Witham, Montana Dept. of Agric., Helena, WA
- D. Nelson, North Dakota Dept. of Agric., Bismarch, ND
- K. Fridley, South Dakota Dept. of Agric., Pierre, SD

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com



April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Re:	<u>USDA #</u> 01-016-26n	Monsanto # 2001-77XRAB
	01.000.10	2001 101XD AD
	01-022-10n	2001-191XRAB
	01-022-11n	2001-192XRAB
	01-022-13n	2001-199XRAB
	01-022-15n	2001-201XRAB
	01-022-17n	2001-204XRAB
	01-022-18n	2001-206XRAB

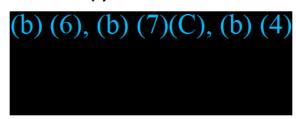


Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (6), (b) (7)(c), (b) (4)

Sincerely yours,



cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

CONFIDENTIAL

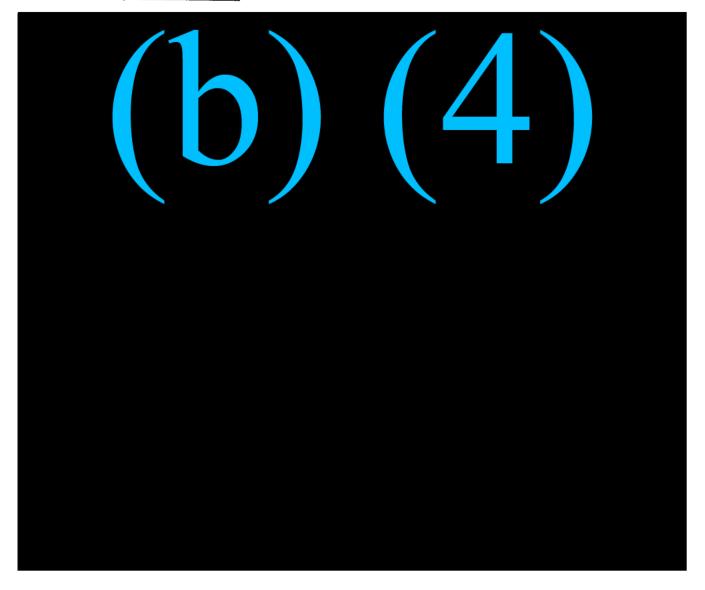
2001 Wheat Field Test Report USDA #01-017-12n Monsanto #2001-144XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

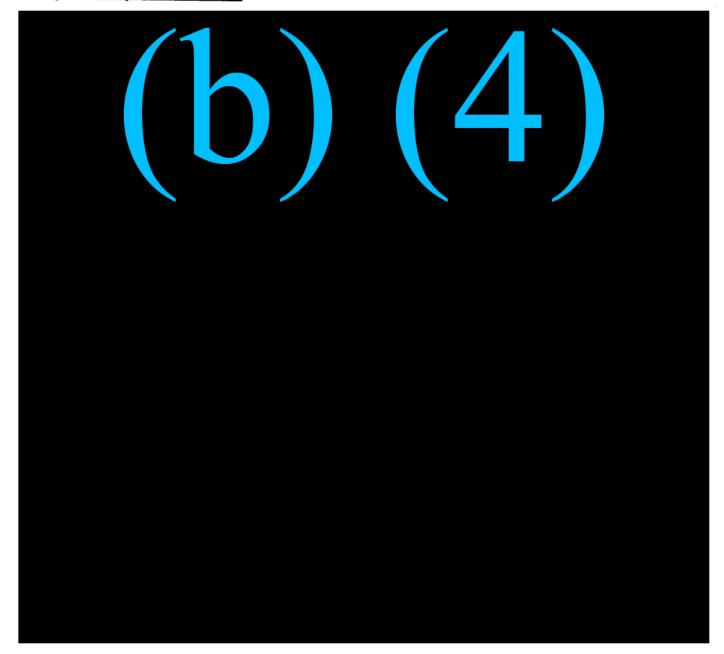
<u>Location</u>	<u>County</u>	<u>State</u>	
2147306820	Clark County	SD	
2147302401	Roberts County	SD	Not Planted
2147303319	Spink County	SD	

Clark County/SD (2147306820)





Spink County/SD (2147303319)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-017-12n Monsanto #2001-144XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	<u>State</u>	
2147306820	Clark County	SD	
2147302401	Roberts County	SD	Not Planted
2147303319	Spink County	SD	

Clark County/SD (2147306820)

Planting Date: 05/02/2001

Harvest Date: 08/01/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Spink County/SD (2147303319)

Planting Date: 05/03/2001

Harvest Date: 08/06/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

December 19, 2003

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Coly (1/27

Re: Our Letter of 4/16/01 concerning the following notifications:

| USDA# | Monsanto # | 2001.77YP AP | 2001.77YP AP |

01-016-26n 2001-77XRAB 01-017-12n 2001-144XRAB 01-022-10n 2001-191XRAB 01-022-11n 2001-192XRAB 01-022-13n 2001-199XRAB 01-022-15n 2001-201XRAB 01-022-17n 2001-204XRAB 01-022-18n 2001-106XRAB

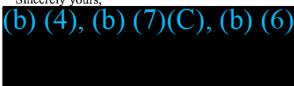
Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.



Please call if you require further information concerning this matter.

Sincerely yours,





December 19, 2003

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

<u>USDA#</u>	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

Bp number: 01-022-10n

App number: 2001-191XRAB Begin movement: 2/17/01 Received: 1/22/01 End movement: 2/17/02 Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 5.00 Effective date: 2/21/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Monsanto Company Address1: Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield, MO Telephone: (b) (6), (b) (7)(C Fax: 636-737-7085 Initial Assign Bp number and initial data entry [/24/0/]* [Review by biotechnologist 2. M Letter of notification to State od-ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * [1 Interstate *Dest*MO *SCR * [Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release *ND 1*SCR * [] [] Enter genes into database Letter of (acknowledgement) denial/withdraw Enter final data into database [a/26/01] 7. If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify reason for tardiness: (KS) did not respond



Monsanto Reference ID

2001-191XRAB

Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-10n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-191XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

ΗТ

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-191XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4) (b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST



(b) (4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-191XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 300 pounds of wheat seed to and from each location.

ORIGIN:

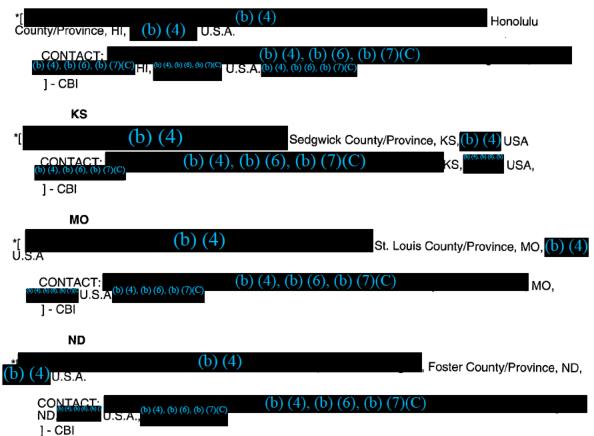
DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

н

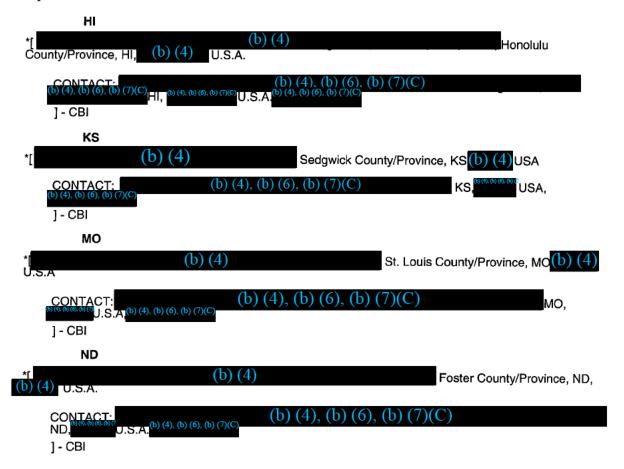


Page 3 of 6

Monsanto Reference ID

2001-191XRAB

Ship To:



Monsanto Reference ID

2001-191XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4) U.S.A., 5 acres.

Foster County/Province, ND,

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7) (b) (4), (b) (6), (b) (7)(C) ND, U.S.A., (b) (4), (b) (6), (b) (7)(C)

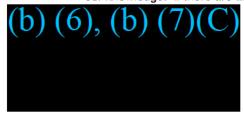
] - CBI



Monsanto Reference ID 2001-191XRAB Monsanto Company
700 Chesterfield Pkwy North
Chesterfield, Missouri 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (lOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

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Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

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The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

Monsanto Reference ID

2001-191XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-10n

1. USDA Reference Number

2. Applicant Reference Number 2001-191XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

FAX EMail

636/737-7085

b) (6), (b) (7)(**0**

monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

нт

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-191XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Disarmed Agrobacterium tumefaciens

Monsanto Reference ID

7. Mode of Transformation

2001-191XRAB

Page 3 of 6

3. Ir	ntroduction	Interstate Movement a	and F	}elea	se	
S	Ship up to 300 pounds of wheat seed to and from each location.					
c	RIGIN:		DES	TINA	TION:	
i	HI, KS, MO, N	ND	HI,	KS,	MO,	ND
Shi	ip From:					
]	HI CBI Deleted] *Honolulu County/Province, HI, U.S./	Α.			
٠		,,,	••			
r	KS CDI Deleted	1 *Onderviel Occupto/Decision I/O LID				
]	CBI Deleted] *Sedgwick County/Province, KS, US/	4			
	МО					
[CBI Deleted] *St. Louis County/Province, MO, U.S.	A			
	ND					
[CBI Deleted] *Foster County/Province, ND, U.S.A.				
Shij	р То:					
	н					
[CBI Deleted] *Honolulu County/Province, HI, U.S.A				

Monsanto Reference ID 2001-191XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

Monsanto Reference ID

2001-191XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

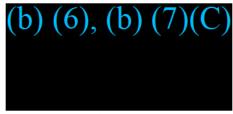
[CBI Deleted] -- Foster County/Province, ND, U.S.A., 5 acres



Monsanto Reference ID 2001-191XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
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http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001



Monsanto Reference ID

2001-191XRAB

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(b) (6), (b) (7)(C) monsanto.com

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700 Chesterfield Parkway North

St. Louis

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63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

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Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-191XRAB

designation of transformed line:

33391

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PV-TXGT10

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(h) (4)

(h) (4

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GENE OF INTEREST

Promoter: CMP3/15 -- ((b) (4) (b) (4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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COMPIDENTIAL

Monsanto Reference ID

2001-191XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 300 pounds of wheat seed to and from each location.

ORIGIN:

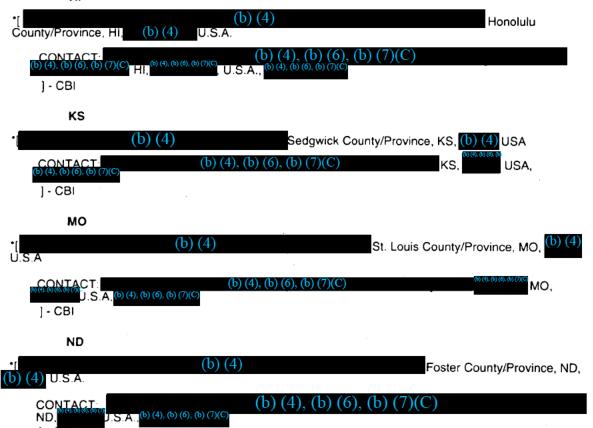
DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

н



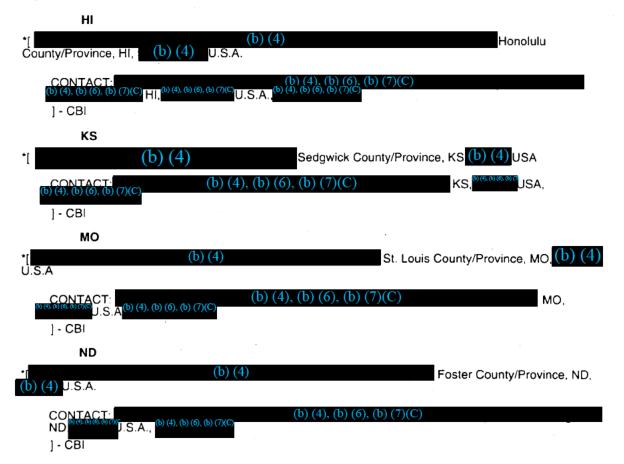
Page 3 of 6

CONTRACTOR

Monsanto Reference ID

2001-191XRAB

Ship To:





Monsanto Reference ID

2001-191XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4) Foster County/Province, ND, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

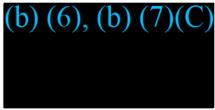
] - CBI



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Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

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Monsanto Reference ID

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 18, 2001

2001-191XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-10n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-191XRAB
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(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

нт

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Sara-

Monsanto Reference ID

2001-191XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal

*5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

CBI Deleted] Promoter: CMP3/I5 -- [

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal

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The part of the proof been been been been been been

Monsanto Reference ID

2001-191XRAB

Page 3 of 6

7.	Widde of Transid	Disarmed Agrobacterium tumeraciens		
8.	Introduction	Interstate Movement and Release		
	Ship up to 300 pounds of wheat seed to and from each location.			
	ORIGIN:	DESTINATION:		
	HI, KS, MO, N	D HI, KS, MO, ND		
:	Ship From:			
	н			
	[CBI Deleted] *Honolulu County/Province, HI, U.S.A.		
	KS			
] *Sedgwick County/Province, KS, USA		
	МО			
] *St. Louis County/Province, MO, U S.A		
	CDI Deletico	1 St. Louis County/ Termines, Wei, C Sarv		
	ND			
	[CBI Deleted] *Foster County/Province, ND, U.S.A.		
:	Ship To:			
	HI			
	[CBI Deleted] *Honolulu County/Province, HI, U.S.A.		



Monsanto Reference ID 2001-191XRAB

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.



Monsanto Reference ID

2001-191XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

CBI Deleted] -- Foster County/Province, ND, U.S.A., 5 acres



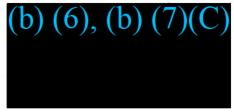
CBI-DELETED

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Monsanto Reference ID 2001-191XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 Dear Mr. Isherwood Jr.: Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c). Bp number 01-022-10n Applicant #: 2001-191XRAB

January 23, 2001

Received:

January 22, 2001

ND

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RE	ESPONSE TO NOTIFICATION
State concurs with APHIS d	determination.
State DOES NOT CONCUR and	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Pptloc01/P4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eliqibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-10n

Applicant #: 2001-191XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION _State concurs with APHIS determination. _State DOES NOT CONCUR and offers the following reasons: Name of State official:_____ Signature: State:____ Rptloc01/R4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number Received:

01-022-10n

Applicant #: 2001-191XRAB

February 21, 2001

Institution: Monsanto

January 22, 2001 Effective: Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official:
Signature:
Date:
State: Rptloc01/P4

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020 January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-10n

Applicant #: 2001-191XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

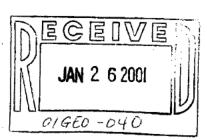
STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons
Name of State official:
Signature:
Date:
State: Rptloc01/R4



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813



January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-10n

Applicant #: 2001-191XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. ·

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE	RESPONSE	TO	NOTIFICATION

AState concurs with Hawaii Dept of Ac	APHIS determination	Please potify Me	C1 01 1
THE DEPT. OF AL	liculture /ol lists	C+ 17 - 3 3	
State DOES NOT CONC	TIP and offers the fac	St., Honolulu, HI	96813.
	or and offers the 10	llowing reasons:	

Name of State Signature:

15 February

State: Hawaii

Rptloc01/R4



An Equal Opportunity Employer

FLE 16 251

Animal and Plant Hearth Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-10n

Applicant #: 2001-191XRAB

Received:

January 22, 2001

 \mathbf{MD}

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO ND

Release destination:

Should you have domments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

wary vacason, Regulatory specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
\mathcal{N}
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State officials Michael & Days
Name of State officials MIChael 6 15000
Signature: (b) (6), (b) (7)(C)
Date: 2(2(3)
m)
State: Rptloc01/R4

- Protecting American Agricultura

An Equal Dipportunity Employer

OR120018 BR 007451



Animai and Plant Health inspection Service

4700 RIVER ROAD Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-10n

Applicant #: 2001-191XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI K5 MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APRIS provide an acknowledgement within 30 days of receipt.

Sincerely

oackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

CC: R. Elliston, PPQ, Fort Collins, CO

745 - Protecting American Agricultura

An Equal Opportunity Employee

JAN 29 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear 1 (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release Notification no. 01-022-10n (2001-191XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

15

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-022-10n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

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916367377085

038/038 00:08:28

– ******



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA





April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Re:	USDA#	Monsanto #
	01-016-26n	2001-77XRAB
	01-017-12n	2001-144XRAB
	01-022-11n	2001-192XRAB
	01-022-13n	2001-199XRAB
	01-022-15n	2001-201XRAB
	01-022-17n	2001-204XRAB
	01-022-18n	2001-206XRAB

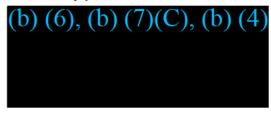


Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (6), (b) (7)(C), (b) (4)

Sincerely yours,



cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

SENDER

DAVID R. NELSON

DIVISION

PLANT PROTECTION

State Entomologist (701) 328-4765

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N

01-016-30N

01-022-10N

OR120018_BR_007457

7 C O . O M

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE

State of North Dakota 600 E. Boulevard Ave. Dept. 602 Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPO

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker

USDA-APHIS-PPQ

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This
 includes all classes of certified seed as well as any grain that may be used as common seed.
 This distance reflects the pollen movement distances recognized by seed certification
 standards.
- 2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b) (7)(C)

OR120018_BR_007458

'1 (



CONFIDENTIAL

December 19, 2003

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Coly Wiles

Re: Our Letter of 4/16/01 concerning the following notifications:

USDA#

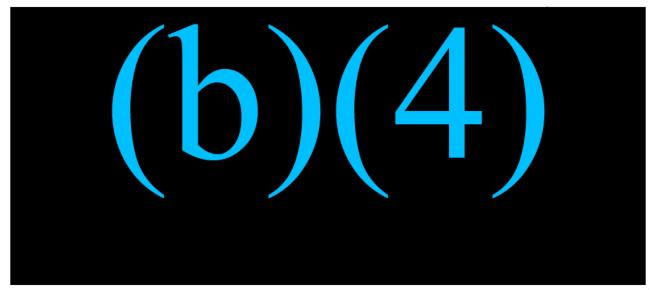
Monsanto #

2001-77YPAB

01-016-26n 2001-77XRAB 01-017-12n 2001-144XRAB 01-022-10n 2001-191XRAB 01-022-11n 2001-192XRAB 01-022-13n 2001-199XRAB 01-022-15n 2001-201XRAB 01-022-17n 2001-204XRAB 01-022-18n 2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.



Please call if you require further information concerning this matter.





CBI-DELETED

December 19, 2003

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

<u>USDA#</u>	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

CONFIDENTIAL

2001 Wheat Field Test Report USDA #01-022-10n Monsanto #2001-191XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

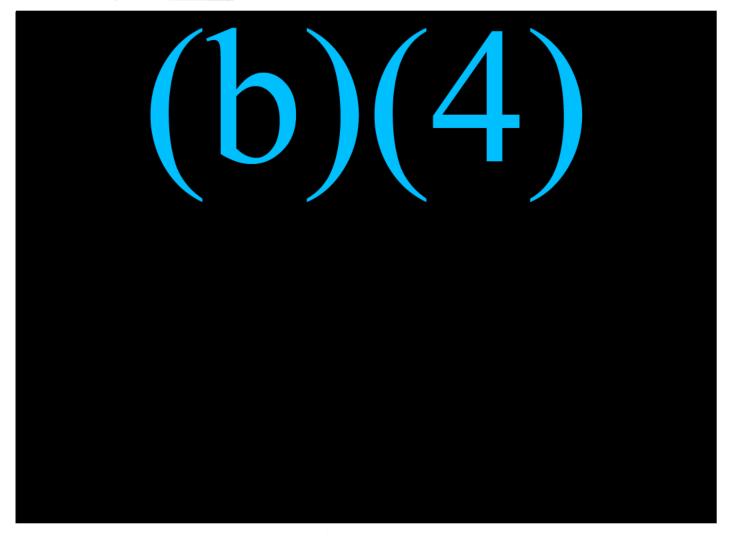
<u>State</u>

1611677957

Foster County

ND

Foster County/ND (1611677957)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report USDA #01-022-10n Monsanto #2001-191XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

1611677957

Foster County

ND

Foster County/ND (1611677957)

Planting Date:

05/11/2001

Harvest Date:

08/14/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

5.

7.

Bp number: 01-022-11n App number: 2001-192XRAB Begin movement: 2/17/01 Received: 1/22/01 2/17/02 End movement: Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 20.00 Effective date: 2/21/01 CBI status: CBI HT - Glyphosate tolerant Phenotype: Comments: (b) (6), (b) (7)(C) Resp person: Parsed name: Address1: Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield MO Telephone: (b) (6), (b) (7)(C Fax: 636-737-7085 Initial 1. [M Assign Bp number and initial data entry [Review by biotechnologist [M Letter of notification to State of -CX [] State response 0/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * Interstate *Dest*MO *SCR * Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release 2*SCR * []

If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify

Enter genes into database

Enter final data into database

[X Letter of (acknowledgement/denial/withdraw

neason for tardiness: (KS) did not respond

Jam July july



CONFIDENTIAL

Monsanto Reference ID

2001-192XRAB

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-11n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-192XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

MO

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

нТ

Phenotype:

Glyphosate tolerant

Ship up to 3000 pounds of wheat seed to and from each location.

Monsanto Reference ID

2001-192XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [(b) (4) (b) (4)

The state of the s

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- I (b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Page 2 of 6

Monsanto Reference ID

2001-192XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

ΗІ

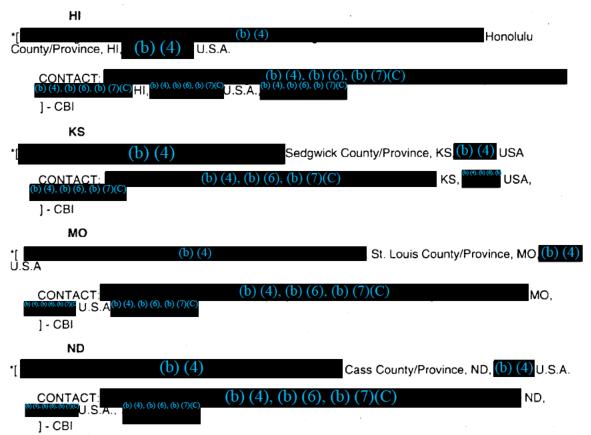


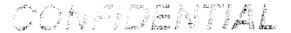
The last the

Monsanto Reference ID

2001-192XRAB

Ship To:





Monsanto Reference ID

2001-192XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

(b) (4) Foster County/Province, ND,

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C) ND (9,0,0,0,0,0,0) U.S.A (b) (4), (b) (6), (b) (7)(C)

Comments: Seed will be moved to release site on day of planting.

] - CBI

(b) (4), (b) (6), (b) (7)(C

(b) (4) Cass County/Province, ND, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) ND (0.6) (0.6) (0.6) (0.6) (0.6) (0.6) (0.6) (0.6) (0.6)

] - CBI

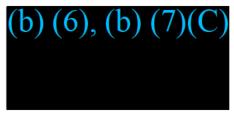


CONFIDENTIAL

Monsanto Reference ID 2001-192XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (lOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services. 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-192XRAB Page 2

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GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-192XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-192XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



CBI-DELETED

Monsanto Reference ID

2001-192XRAB

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000

PHONE (314) 694-1000 FAX (636) 737-7085

MONSANTO COMPANY

http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-11n

1. USDA Reference Number

2. Applicant Reference Number 2001-192XRAB

3. Applicant/Responsible Party

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

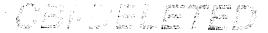
Phenotypic Category:

нт

Phenotype:

Glyphosate tolerant

Ship up to 3000 pounds of wheat seed to and from each location.



Monsanto Reference ID

2001-192XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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From the form of t

Monsanto Reference ID

2001-192XRAB

Page 3 of 6

7.	. Mode of Transformation Disarmed Agrobacterium tumefaciens		efaciens		
8.	Introduction	•	Interstate Movement a	nd Rele	ease
	Ship up to 3000 pounds of wheat seed toa nd from each location.				
	ORIGIN:			DESTIN	IATION:
	HI, KS, MO, I	ND		HI, KS	S, MO, ND
S	hip From:				
	н				
	(CBI Deleted] *Honolulu Cou	inty/Province, HI, U.S.A	١.	
	KS				
1	CBI Deleted] *Sedgwick Co	unty/Province, KS, USA		
	MO				
ſ) *St. Louis Cou	nty/Province, MO, U.S.	Δ	
٠	,	,	,		
	ND				
[1 *Cass County/	Province, ND, U.S.A.		
ı	CDI Deleted	j Cass County/	Province, ND, O.S.A.		
Ç1	sin Tax				
Si	nip To:				
[HI CBI Deleted	1 *Honolulu Cour	nty/Province, HI, U.S.A.		
ŧ	CDI Deleten	j Honolulu Cour	ny/r-rovince, mi, U.S.A.		



Monsanto Reference ID

2001-192XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

CBI Deleted] -- *Cass County/Province, ND, U.S.A.



Monsanto Reference ID

2001-192XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

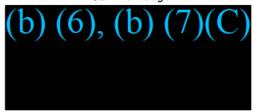


MONSANTO COMPANY
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CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Monsanto Reference ID 2001-192XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001



Monsanto Reference ID

2001-192XRAB

MONSANTO COMPANY

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January 18, 2001

Permit Unit

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- 1. USDA Reference Number
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Phone

636/737-7085

FAX **EMail**

monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

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Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

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Monsanto Reference ID

2001-192XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- I

(b) (4)

CBI

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(b) (4)

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DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

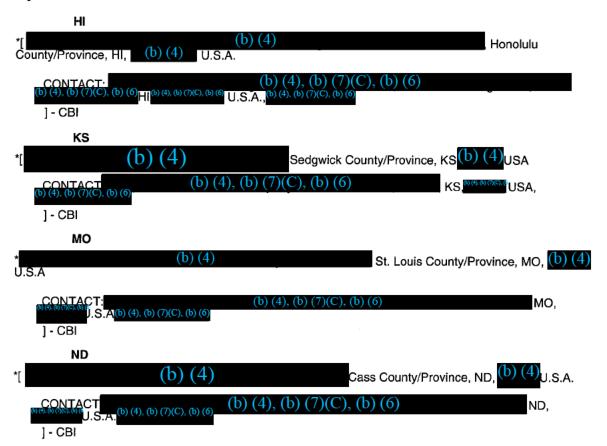
Ship From:



Monsanto Reference ID

2001-192XRAB

Ship To:



Monsanto Reference ID

2001-192XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

(b) (4)

Foster County/Province, ND,

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (7)(C), (b) (6) ND

(b) (4), (b) (7)(C), (b) (6) ND

(c) (4), (b) (7)(C), (b) (6) ND

(d) (4), (b) (7)(C), (b) (6) ND

(e) (4), (b) (7)(C), (b) (6) ND

(f) (6) (7)(C), (b) (6) ND

(g) (6) (7)(C), (b) (6) ND

(g) (7)(C), (b) (7)(C),

(b) (4) Cass County/Province, ND, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (7)(C), (b) (6)
(D) (A), (b) (

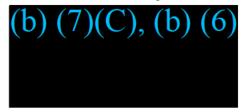
] - CBI



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CBI Justification Notification 2001-192XRAB Page 2

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CBI Justification Notification 2001-192XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID

2001-192XRAB

Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 18, 2001

Monsanto Reference IL

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-11n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-192XRAB
- 3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX EMail 636/737-7085

(b) (7)(C), (b) (6) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Ship up to 3000 pounds of wheat seed to and from each location.

Monsanto Reference ID

2001-192XRAB

designation of transformed line:

33391

Constructs: PV-TX

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Disarmed Agrobacterium tumefaciens

Monsanto Reference ID

7. Mode of Transformation

2001-192XRAB

8. Introduction

Page 3 of 6

3. Introduction			Interstate Movement and Release		
Ship up to 3000 po		ip up to 3000	ounds of wheat seed toa nd from each location.		
	OR	IGIN:	DESTINATION:		
HI, KS, MO, ND			D HI, KS, MO, NE)	
S	Ship	From:			
		ні			
	[CBI Deleted] *Honolulu County/Province, HI, U.S.A.		
		KS			
	[CBI Deleted] *Sedgwick County/Province, KS, USA		
		MO			
	[CBI Deleted] *St. Louis County/Province, MO, U.S.A		
		ND			
	[CBI Deleted] *Cass County/Province, ND, U.S.A.		
Ship To:					
		HI			
	Ī.	CBI Deleted] *Honolulu County/Province, HI, U.S.A.		

Monsanto Reference ID 2001-192XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

Monsanto Reference ID

2001-192XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres



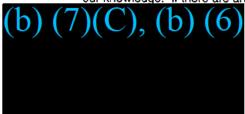
MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-192XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official:
Signature:
Date:
State:Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility . criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION	
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following re	easons:
Name of State official:	
Signature:	.
Date:	
State: Rptloc01/R4	L

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

editary zi, zoor

Table to Table Table

MO ND

Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

S

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Ouarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STA	TE RESPONSE TO NOTIFICATION
State concurs with AP	HIS determination.
State DOES NOT CONCUR	and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official:
Signature:
Date:
State: Potloc01/P4



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 23, 2001

PLANT QUARANTINE BRANCH

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (7)(C), (b) (6)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA
STATE RESPONSE TO NOTIFICATION
Xstate concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813state DOES NOT CONCUR and offers the following reasons:
Name of State official: Carol L. Okada
Signature:(b) (7)(C), (b) (6)
Date: 20 February 2001
State: Hawaii Rptloc01/R4



An Equal Opportunity Employer

Animai and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION					
V)					
State concurs with APHIS determination.					
State DOES NOT CONCUR and offers the following reasons:					
Name of Stone official A Michael & Mark					
Name of State official:					
(b) (7)(C) (b) (6)					
Signature: $(b) (7)(C), (b) (6)$					
Signature:					
Date: (C)					
State: Rotloc01/R4					
State: Rptloc01/R4					

165 - Protecting Amencian Agnoulture

An Equal Opposiumity Employee

OR120018 BR 007503



Animal and Plant Health inspection Service

4700 River Road Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bo number

01-022-11n

Applicant #: 2001-192XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Cuarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE	TO NOTIFICATION
State concurs with APHIS determi	nation,
State DOES NOT CONCUR and offers	the following reasons:
Name of State official: DAVID R	NEWON
Name of State official: DAVID R Signature: (b) (7)(C), (b) (6)	
Date: /-29-0/	
State: 1	Rptloc01/R4



An Equal Opportunity Employee

JAN 29 2001

(b) (7)(C), (b) (6)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear(b)(7)(C), (b)(6)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release Notification no. 01-022-11n (2001-192XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|5|

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-022-11n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

COMM. ABBR NO. STN NO.

STATION NAME/TEL NO.

PAGES DURATION

201

ΠK

916367377085

238/238 20:08:28

— жжжжж →



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

February 23, 2001

Monsanto Company

700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Motification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA R. Stoaks, PPQ, SCR, WR, Sacramento, CA



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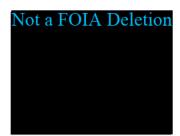


April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Re:	USDA#	Monsanto #
	01-016-26n	2001-77XRAB
	01-017-12n	2001-144XRAB
	01-022-10n	2001-191XRAB
	01-022-13n	2001-199XRAB
	01-022-15n	2001-201XRAB
	01-022-17n	2001-204XRAB
	01-022-18n	2001-206XRAB

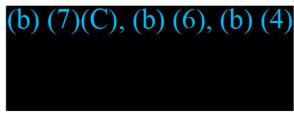


Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (7)(C), (b) (6), (b) (4)

Sincerely yours,



cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

SENDER

DAVID R. NELSON

DIVISION

PLANT PROTECTION

State Entomologist (701) 328-4765

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N

01-016-30N

01-022-10N

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota 600 E. Boulevard Ave. Dept. 602 Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPO

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker

USDA-APHIS-PPQ

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

(b) (7)(

(b)(6)

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- 1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the polien movement distances recognized by seed certification standards.
- 2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b) (7)(C)

2001 Wheat Field Test Report USDA #01-022-11n Monsanto #2001-192XRAB

September 26, 2002

Biotech Field Compliance Team Monsanto Company

Location 1611677957 2147303287 **County**

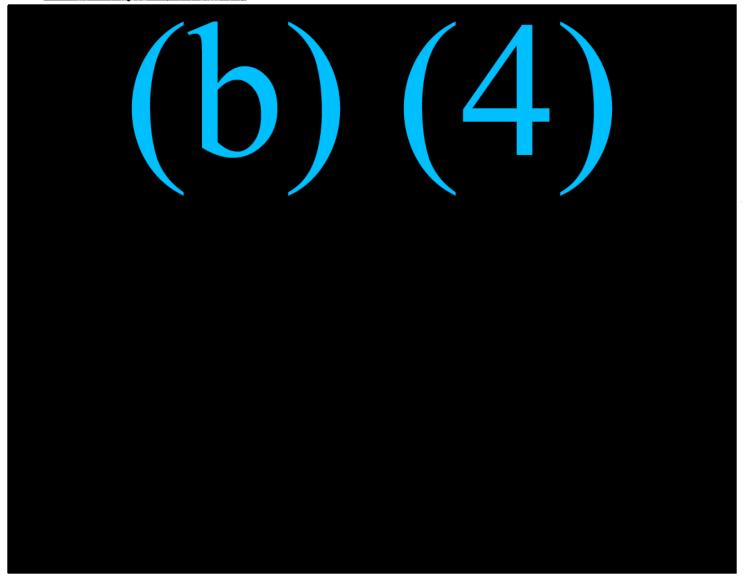
Foster County

Cass County

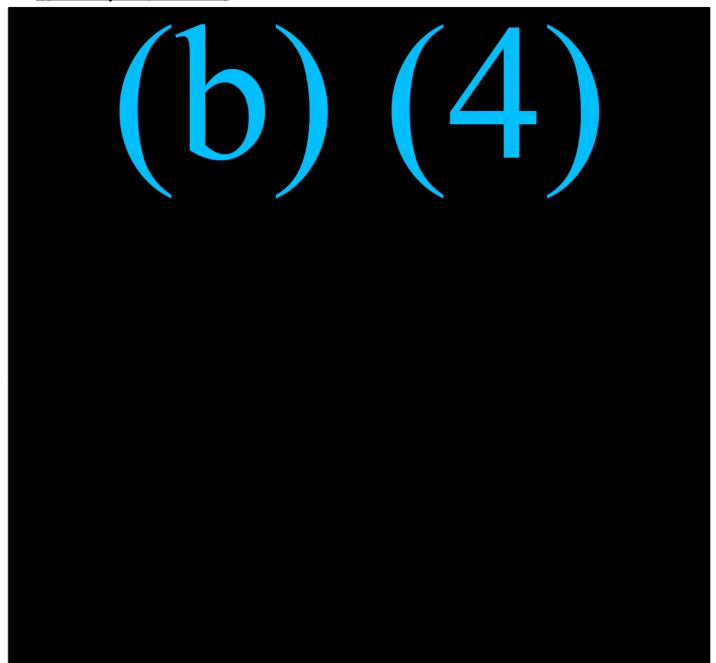
State

ND ND

Foster County/ND (1611677957)



Cass County/ND (2147303287)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food. & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-022-11n Monsanto #2001-192XRAB

September 26, 2002

Biotech Field Compliance Team Monsanto Company

LocationCountyState1611677957Foster CountyND2147303287Cass CountyND

Foster County/ND (1611677957)

Planting Date: 05/11/2001

Harvest Date: 08/14/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Cass County/ND (2147303287)

Planting Date: 05/18/2001

Harvest Date: 08/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]



December 19, 2003

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Colycias

Re: Our Letter of 4/16/01 concerning the following notifications:

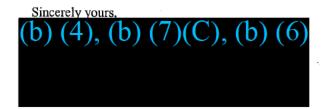
	USDA#		Monsanto #
	01-016-26n	\ .	2001-77XRAB
/	01-017-12n	\	2001-144XRAB
/	01-022-10n	1	2001-191XRAB
П	01-022-11n	₹,	2001-192XRAB
1 1	01-022-13n	1	2001-199XRAB
VI.	01-022-15n	1	2001-201XRAB
7	01-022-17n	/	2001-204XRAB
\	01-022-18n		2001-106XRAB
\		/	

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.



Please call if you require further information concerning this matter.





December 19, 2003

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

<u>USDA#</u>	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

____________________________________ Bp number: 01-022-15n

App number: 2001-201XRAB Begin movement: 2/17/01 Received: 1/22/01 End movement: 2/17/02 Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 40.00 Effective date: 2/21/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield Telephone: Fax: 636-737-7085 Initial Date Assign Bp number and initial data entry [N Review by biotechnologist Letter of notification to State od -ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * [Interstate *Dest*MO *SCR * Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release *ND 4*SCR * [] [] Enter genes into database 6. Letter of acknowledgement denial/withdraw 7. Enter final data into database [KX.nO] [2/26/0] If deny, reason: Address incomplete, Signature mismatch,

Ph category, Phenotype, Gene, Donor, Marker, Does not qualify

Reason for tandiness - (KS) did not respond

Bp number: 01-022-13n

App number: 2001-199XRAB Begin movement: 2/17/01 Received: 1/22/01 End movement: 2/17/02 Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 5.00 Effective date: 2/21/01 CBI status: CBI HT - Glyphosate tolerant Phenotype: Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield. MO Telephone: (b) (6), (b) (7)(C Fax: 636-737-7085 Initial [N] Assign Bp number and initial data entry [Review by biotechnologist [1/24/01]* 1 Letter of notification to State red ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * [Interstate *Dest*MO *SCR * 1 Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release *ND 1*SCR * [] Ε 5. Enter genes into database 6. ${\it extit{L}}$ etter of/acknowledgement ${\it extit{M}}$ denial/withdraw 7. Enter final data into database If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker,

reason fren tardiness: (KS) did mot respond

All of my 1/3



Monsanto Reference ID

2001-199XRAB

Monsanto Company

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-13n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-199XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

ΗТ

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-199XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

(b)(4)

(b)(4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-199XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

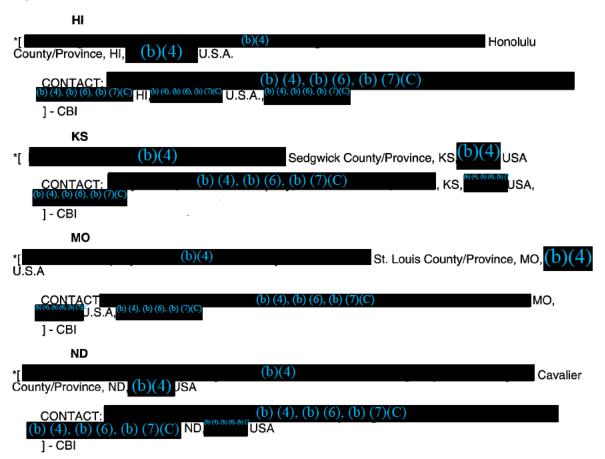
HI



Monsanto Reference ID

2001-199XRAB

Ship To:



Monsanto Reference ID

2001-199XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[(b)(4) Cavalier County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

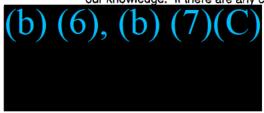
] - CBI



Monsanto Reference ID 2001-199XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Monsanto Reference ID

2001-199XRAB

Permit Unit

January 18, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-13n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-199XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX EMail 636/737-7085 (b) (6), (b) (7)(C)₂ monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-199XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBi Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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Disarmed Agrobacterium tumefaciens

Monsanto Reference ID

7. Mode of Transformation

2001-199XRAB

8. Introduction

Page 3 of 6

3.	Introduction	Interstate Movement an	d Releas	se	
	Ship up to 3000	pounds of wheat seed to and from each local	ation.		
	ORIGIN:	D	ESTINA	TION:	
	HI, KS, MO, 1	ND H	HI, KS,	MO,	ND
S	Ship From:				
	HI				
	[CBI Deleted] *Honolulu County/Province, HI, U.S.A.			
	KS				
	[CBI Deleted] *Sedgwick County/Province, KS, USA			
	МО				
	[CBI Deleted] *St. Louis County/Province, MO, U.S.A			
	ND				
ı	CBI Deleted] *Cavalier County/Province, ND, USA			
SI	hip To:				
	н				
[CBI Deleted] *Honolulu County/Province, HI, U.S.A.			

Monsanto Reference ID

2001-199XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cavalier County/Province, ND, USA

Monsanto Reference ID

2001-199XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Cavalier County/Province, ND, USA, 5 acres

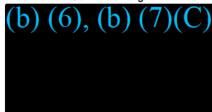


Monsanto Company 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Monsanto Reference ID 2001-199XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 18, 2001

Monsanto Reference ID

2001-199XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

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- 1. USDA Reference Number
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(b) (6), (b) (7)(C)

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monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

)

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

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Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI

Monsanto Reference ID

2001-199XRAB

designation of transformed line:

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GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)
(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4) csi

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Control of the first than the first

Disarmed Agrobacterium tumefaciens

Monsanto Reference ID

7. Mode of Transformation

2001-199XRAB

8. Introduction Interstate Movement and Release Ship up to 3000 pounds of wheat seed to and from each location. ORIGIN: **DESTINATION:** HI, KS, MO, ND HI, KS, MO, ND Ship From: НΙ Honolulu County/Province, HI, (b) (4)CONTACT: (b) (4), (b) (6), (b) (7)(C)] - CBI KS Sedgwick County/Province, KS CONTACT b) (4), (b) (6), (b) (7)(C] - CBI MO St. Louis County/Province, MO. (b) (4) CONTACT:] - CBI ND Cavalier County/Province, ND, (b) (4) USA CONTACT:

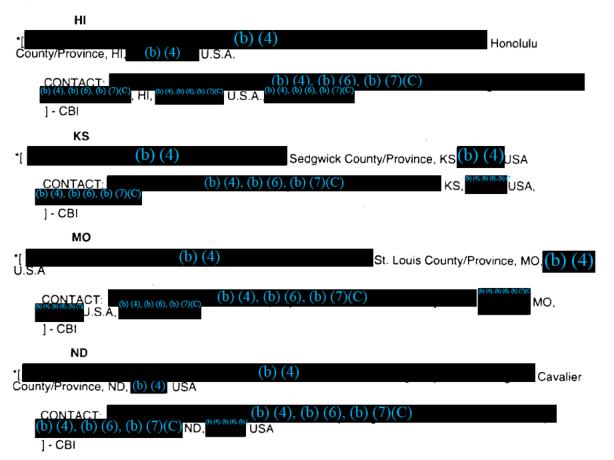
] - CBI

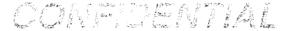
COSTRUMNIAL

Monsanto Reference ID

2001-199XRAB

Ship To:





Monsanto Reference ID

2001-199XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[(b) (4) Cavalier County/Province, ND, USA, 5 acres.

(b) (4), (b) (6), (b) (7)(C)

(h) (4) (b) (6), (b) (7)(C)

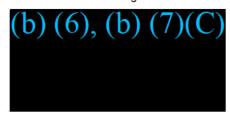
] - CBI



Monsanto Reference ID 2001-199XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services. 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

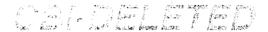
The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID

2001-199XRAB

Permit Unit

January 18, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-13n

1. USDA Reference Number

2. Applicant Reference Number 2001-199XRAB

3. Applicant/Responsible Party

Phone

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

The same that th

Monsanto Reference ID

2001-199XRAB

designation of transformed line:

33391

Constructs: P\

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal Sandy wylshikimate. 3 phosphate synthese gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium

tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]



CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal Senting Pay is liking a sample of the Section (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

The part of the pa

Monsanto Reference ID

2001-199XRAB

Page 3 of 6

7. N	lode of Trans	formation	Disarmed Agrobacteriu	ım tumef	aciens	S
8. lı	ntroduction		Interstate Movement ar	nd Relea	se	
5	Ship up to 3000	pounds of wheat se	eed to and from each loo	cation.		
		•				
	ORIGIN:		ι	DESTINA	TION:	
1	HI, KS, MO, I	ND		HI, KS,	MO,	ND
Sh	ip From:					
	н					
[CBI Deleted] *Honolulu Cou	inty/Province, HI, U.S.A.			
	KS					
[CBI Deleted] *Sedgwick Co	unty/Province, KS, USA			
	МО					
[CBI Deleted] *St. Louis Cou	nty/Province, MO, U.S.A			
	ND					
[CBI Deleted] *Cavalier Cour	ity/Province, ND, USA			
Ship	To:					
	н					
[CBI Deleted] *Honolulu Cour	ity/Province, HI, U.S.A.			

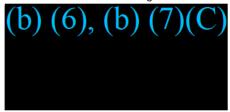


Monsanto Company
700 Chesterfield Pkwy North
Chesterfield, Missouri 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Monsanto Reference ID 2001-199XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-13n

Applicant #: 2001-199XRAB

Received: Janu

January 22, 2001

Effective: February 21, 2001

Recipient:

Wheat

Institution: Monsanto

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION	· .
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following reason	ons:
Name of State official:	
Signature:	
Date:	
State: Rptloc01/R4	

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-13n Applicant #: 2001-199XRAB Received: January 22, 2001 Effective: February 21

Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: NI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
DIAIE RESPONSE TO MOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official:
Signature:
Date:
State: Phtlog01/P4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-13n

Applicant #: 2001-199XRAB

Received:

January 22, 2001

Effective: February 21, 2001 Recipient: Wheat

Institution: Monsanto Recipient:

ND

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

15

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official:
Signature:
Date:
State:

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-13n January 22, 2001 Received:

Applicant #: 2001-199XRAB Effective: February 21, 2001

Wheat

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official:
Signature:
Date:
State: Rptloc01/R4



Animal and Plant Health Inspection Service 4700 RIVER ROAD Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-13n

Applicant #: 2001-199XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE	RESPONSE	TO	NOTIF:	ICATIO	N

. X	_State	concur	s with	APHIS	determi	nation	ı. Please	notify	Ms. C	aro1	Okada.
	Hawaii	L Dept.	of Agi	ricultu	re. 701	Ilalo	St. Hon	olulu. I	TT 968	313.	<u>-</u>
	_State	DOES N	от сой	CUR and	d offers	the f	collowing	reasons	3;		

Name of State official: Carol L. Okada

Signature:

Date: 20 February 2001

State: Hawaii

Rptloc01/R4



Ап Един Орриничку Еггерия



Animal and Plant Heatin Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-13n

Applicant #: 2001-199XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DORS NOT CONCUR and offers the following reasons:
ame of State official: Miles
ignature: (D) (O), (D) (/)(C)
ate: 2/2/01
Rptloc01/R4



An Equal Opportunity Employer

5 2001 FEB.



Animai and Plant Hearth Inspection Service

4700 River Road Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-13n

Applicant #: 2001-199XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MC ND Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State Official:) AVID R NEW ON
Name of State Official: AVID R NELLON Signature: (b) (6), (b) (7)(C)
Date: /- 29 - 0/
State: Rptloc01/R4



JAN 29 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release
Notification no. 01-022-13n (2001-199XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-022-13n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

001.

UK 🕿

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238/038 00:08:28

– skokokok –



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

$p_{ear}(b)(6), (b)(7)(C)$

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA





April 16, 2001

Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Re:	USDA # 01-016-26n 01-017-12n 01-022-10n 01-022-11n	Monsanto # 2001-77XRAB 2001-144XRAB 2001-191XRAB 2001-192XRAB
	01-022-15n 01-022-17n 01-022-18n	2001-201XRAB 2001-204XRAB 2001-206XRAB

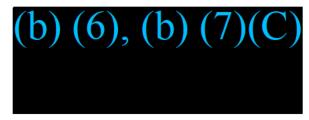


Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (6), (b) (7)(C)

Sincerely yours,



ce: Dr. Ralph Stoaks USDA, APHIS, PPQ

NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

(0)(0),(0)

SENDER

DAVID R. NELSON

DIVISION

PLANT PROTECTION

State Entomologist (701) 328-4765

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N

01-016-30N

01-022-10N

OR120018_BR_007559

7CO 'AN

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota 600 E. Boulevard Ave. Dept. 602

Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPQ

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker USDA-APHIS-PPO

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- 1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
- 2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.
- CC William Pilacinski, Monsanto Regulatory Affairs Manager Pricilla E. Hunter, Monsanto Compliance Specialist

2001 Wheat Field Test Report USDA #01-022-13n Monsanto #2001-199XRAB

September 26, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

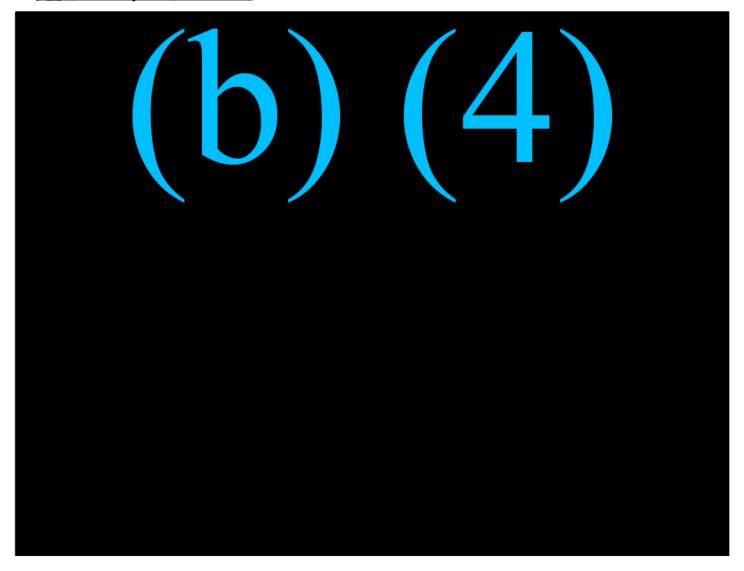
State

2147307343

Cavalier County

ND

Cavalier County/ND (2147307343)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food. & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-022-13n Monsanto #2001-199XRAB

September 26, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

2147307343

Cavalier County

ND

Cavalier County/ND (2147307343)

Planting Date:

05/09/2001

Harvest Date: 08/21/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

December 19, 2003

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Colyphiles

Re: Our Letter of 4/16/01 concerning the following notifications:
USDA#

Monsanto #

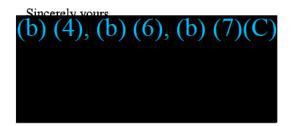
	1	<u>USDA#</u>		Monsanto #
	l	01-016-26n	1	2001-77XRAB
1	1	01-017-12n	\	2001-144XRAB
II		01-022-10n	1	2001-191XRAB
П	1	01-022-11n	- 1	2001-192XRAB
۱ ۱		01-022-13n	- *: J	2001-199XRAB
	١	01-022-15n	- /	2001-201XRAB
	1	01-022-17n	/	2001-204XRAB
	\	01-022-18n	/	2001-106XRAB
	_ \		/	,

Dear Mr. Roman

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.



Please call if you require further information concerning this matter.





December 19, 2003

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

USDA#	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

Bp number: 01-022-15n

App number: 2001-201XRAB Begin movement: 2/17/01 Received: 1/22/01 End movement: 2/17/02 Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 40.00 Effective date: 2/21/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield Telephone: Fax: 636-737-7085 Initial Date Assign Bp number and initial data entry [N Review by biotechnologist Letter of notification to State od -ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * [Interstate *Dest*MO *SCR * Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release *ND 4*SCR * [] [] Enter genes into database 6. Letter of acknowledgement denial/withdraw 7. Enter final data into database [KX.nO] [2/26/0] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker,

Reason for tandiness - (KS) did not respond

Does not qualify



Monsanto Reference ID

2001-201XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-15n

1. USDA Reference Number

2. Applicant Reference Number 2001-201XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)

Phone

b) (6), (b) (7)(C

FAX

636/737-7085

EMail

b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

CBI

Constructs: PV-TXGT13

GENE OF INTEREST

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b) (4)

CBI

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- (b) (4) (CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

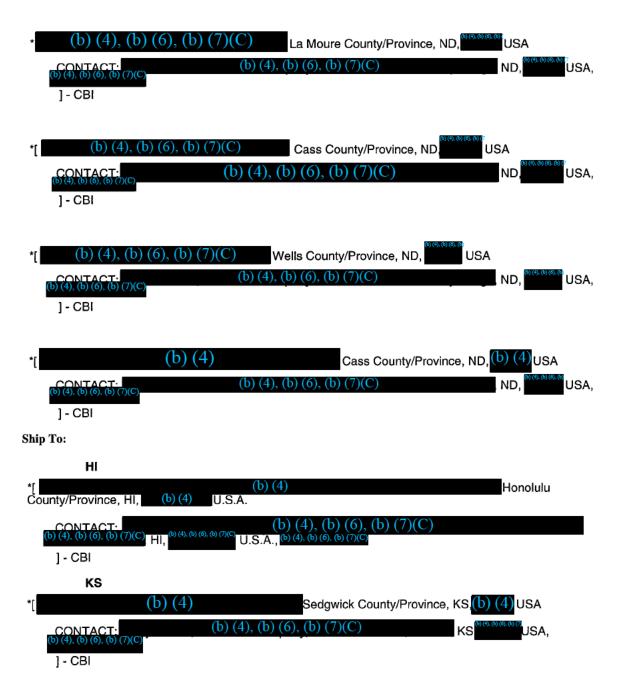
HI, KS, MO, ND

Ship From:

ΗІ Honolulu *[County/Province, HI, (b) (4) U.S.A. (b) (4), (b) (6), (b) (7)(C) U.S.A] - CBI KS Sedgwick County/Province, KS, CONTACT: b) (4), (b) (6), (b) (7)(0 MO St. Louis County/Province, MO, (b) (4) b) (4), (b) (6), (b) (7)(C] - CBI ND Cass County/Province, ND, USA USA,] - CBI

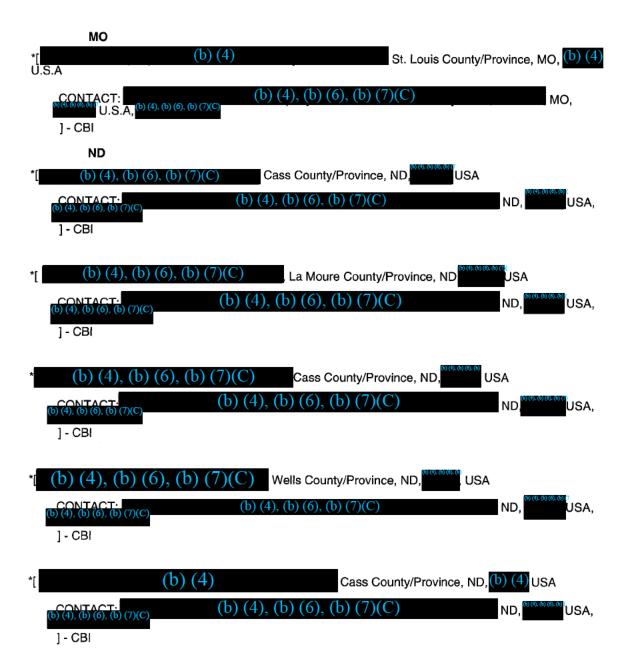
Monsanto Reference ID

2001-201XRAB



Monsanto Reference ID

2001-201XRAB



Monsanto Reference ID 2001-201XRAB Release Site: NUMBER OF STATES/TERRITORIES AND SITES: ND (4) ND (b) (4), Cass County/Province, ND, USA, 10 acres. RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) ND, (b) (7)(C) USA, (b) (6), (b) (7)(C) 1 - CBI (b) (4), (b) (6), (b) (7)(C) La Moure County/Province, ND, USA, 10 acres. RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) ND, (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)] - CBI Cass County/Province, ND, USA, 10 acres. RESPONSIBLE PERSON/RESEARCHER: b) (4), (b) (6), (b) (7)(C) ND, (b) (6), (b) (7)(C)] - CBI Wells County/Province, ND, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: b) (4), (b) (6), (b) (7)(C) (D) (0.000.01 | 1.54 (b) (4), (b) (6), (b) (7)(C

USA,

Page 9 of 10

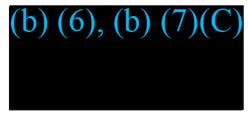
] - CBI



Monsanto Reference ID 2001-201XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-201XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-201XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-201XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 18, 2001

Monsanto Reference ID

2001-201XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-15n

1. USDA Reference Number

2. Applicant Reference Number 2001-201XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

EMail

636/737-7085 b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

ΗТ

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs:

PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

7. Mode of Transformation	Disarmed Agrobacterium tumefaciens
8. Introduction	Interstate Movement and Release
Ship up to 3000 pounds	of wheat seed to and from each location.
ORIGIN:	DECTINATION.
HI, KS, MO, ND	DESTINATION: HI, KS, MO, NE
Ship From:	
HI	
[CBI Deleted] *Ho	nolulu County/Province, HI, U.S.A.
KS	
[CBI Deleted] *Se	dgwick County/Province, KS, USA
140	
MO [CBI Deleted] *St.	Louis County/Province, MO, U.S.A
[20010 000111 3 /1 10111100; 11101; 0101111
ND	
[CBI Deleted] *Cas	ss County/Province, ND, USA
CBI Deleted 1 *La	Moure County/Province ND USA

Page 6 of 10

Monsanto Reference ID 2001-201XRAB

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[ CBI Deleted ] -- *Cass County/Province, ND, USA
 [ CBI Deleted ] -- *Wells County/Province, ND, USA
 [ CBI Deleted ] -- *Cass County/Province, ND, USA
Ship To:
 [ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
```

Monsanto Reference ID

2001-201XRAB

ND

- [CBI Deleted] -- *Cass County/Province, ND, USA
- [CBI Deleted] -- *La Moure County/Province, ND, USA
- [CBI Deleted] -- *Cass County/Province, ND, USA
- [CBI Deleted] -- *Wells County/Province, ND, USA
- [CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID

2001-201XRAB

Release Site: NUMBER OF STATES/TERRITORIES AND SITES: ND (4)			
Į	ND CBI Deleted] Cass County/Province, ND, USA, 10 acres	
[CBI Deleted] La Moure County/Province, ND, USA, 10 acre	
[CBI Deleted] Cass County/Province, ND, USA, 10 acres	

[CBI Deleted] -- Wells County/Province, ND, USA, 10 acres



Monsanto Reference ID 2001-201XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company January 18, 2001



CONFIDENTIAL

Monsanto Reference ID 2001-201XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-15n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-201XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

Phone FAX

EMail

(0) (6), (0) (7)(0

@monsanto.com

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

MO

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto	Reference	ID
----------	-----------	----

2001-201XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

(b) (4)

CBI

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto	Reference	ID
----------	-----------	----

2001-201XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (b) (4) (CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b) (4)

CONFIGNORY TO LOS

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S9240, TA_S9719

Constructs:

PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b) (4)

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 --

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-201XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

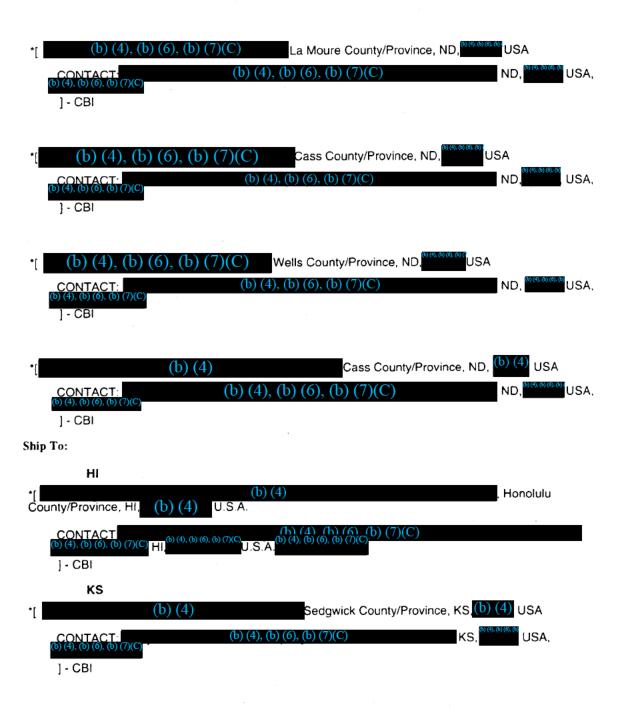
Ship From:

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Page 6 of 10

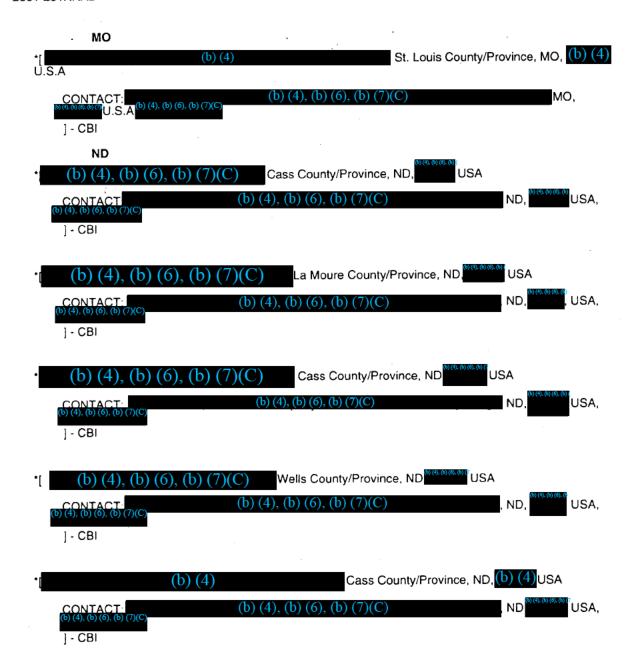
Monsanto Reference ID 2001-201XRAB



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Monsanto Reference ID

2001-201XRAB



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Monsanto Reference ID 2001-201XRAB Release Site: NUMBER OF STATES/TERRITORIES AND SITES: ND (4) ND (b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)] - CBI La Moure County/Province, ND, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)] - CBI Cass County/Province, ND, USA, 10 acres. RESPONSIBLE PERSON/RESEARCHER b) (4), (b) (6), (b) (7)(C) ND (6, 6) (6, 8) (7) (2) (4), (b) (6), (b) (7)(C)] - CBI Wells County/Province, ND, USA, 10 acres. RESPONSIBLE PERSON/RESEARCHER b) (4), (b) (6), (b) (7)(C) ND. (0) (0) (0) (0) (1) (1) (2) (4), (b) (6), (b) (7)(C)

Page 9 of 10

] - CBI

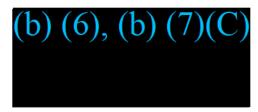


CONFIDENTIAL

Monsanto Reference ID 2001-201XRAB Monsanto Company
700 Chesterfield Pkwy North
Chesterfield, Missouri 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (lOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-201XRAB Page 2

Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC. No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification Notification 2001-201XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-201XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID 2001-201XRAB 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

MONSANTO COMPANY

Permit Unit

January 18, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-15n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-201XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S0317, TA_S0635, TA_S01081, TA_-S2520, TA_S5450,

Constructs:

PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal Standard S

Not a FOIA Deletion

CBI

Terminator: M1 3' -- [CBI Deleted]

See has been been been been been been been

Monsanto Reference ID

2001-201XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215, TA_S10430

Constructs:

PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthese gene (CP4) from an Agrobacterium species, strain

Not a FOIA Deletion

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



Monsanto Reference ID

2001-201XRAB

7.	Мс	ode. of Transfo	rmation	Disarmed Agrobacte	rium t	umefa	aciens	
8.	Int	roduction		Interstate Movement	and F	Releas	se	
	Sh	nip up to 3000 p	oounds of wheat se	eed to and from each	locatio	on.		
	OF	RIGIN:			DES	TINA	TION:	
	Н	I, KS, MO, N	D		HI,	KS,	MO,	ND
9	Ship	From:			•			
		HI						
	[CBI Deleted] *Honolulu Co	unty/Province, HI, U.S	S.A.			
		KS						
	1	CBI Deleted] *Sedgwick Co	ounty/Province, KS, U	SA			
		МО						
	[1 *St. Louis Co.	unty/Province, MO, U.	SΔ			
	l	CDI Deleteu) St. Louis Co.	Jitty/i Tovince, Mo, O.	J.A			
		ND						
	[CBI Deleted] *Cass County	/Province, ND, USA				
	[CBI Deleted] *La Moure Co	ounty/Province, ND, U	SA			

Page 6 of 10

Monsanto Reference ID 2001-201XRAB

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[ CBI Deleted ] -- *Cass County/Province, ND, USA
[ CBI Deleted ] -- *Wells County/Province, ND, USA
[ CBI Deleted ] -- *Cass County/Province, ND, USA
Ship To:
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
   CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
```

Monsanto Reference ID

2001-201XRAB

ND

- [CBI Deleted] -- *Cass County/Province, ND, USA
- [CBI Deleted] -- *La Moure County/Province, ND, USA
- [CBI Deleted] -- *Cass County/Province, ND, USA
- [CBI Deleted] -- *Wells County/Province, ND, USA
- [CBI Deleted] -- *Cass County/Province, ND, USA



Monsanto Reference ID

2001-201XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (4)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- La Moure County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- Wells County/Province, ND, USA, 10 acres

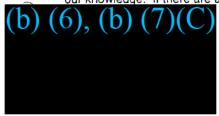


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Monsanto Reference ID 2001-201XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

Mr. Myron Isherwood Jr., Manager January 23, 2001 Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 Dear Mr. Isherwood Jr.: Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c). Bp number 01-022-15n Applicant #: 2001-201XRAB Received: January 22, 2001 Effective: February 21, 2001 Institution: Monsanto Recipient: Wheat Interstate destination: HI KS MO ND Release destination: ND Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date. It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. Sincerely, Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine Enclosure cc: R. Stoaks, PPQ, Sacramento, CA STATE RESPONSE TO NOTIFICATION ____State concurs with APHIS determination.

Rptloc01/R4

_State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:____

State:____

Date:_____

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-15n

Applicant #: 2001-201XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
State concurs wit	h APHIS determination.
State DOES NOT CO	NCUR and offers the following reasons:
Name of State official:_	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-15n

Applicant #: 2001-201XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

ST	PATE RESPONSE TO NOTIFICATION
State concurs with A	APHIS determination.
State DOES NOT CONCU	JR and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Pptloc01/P4

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-15n

Applicant #: 2001-201XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STA	TE RESPONSE TO NOTIFICATION
State concurs with AP	HIS determination.
State DOES NOT CONCUR	and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4



Animal and Plant Health Inspection Service 4700 River Road Rivergale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-15n

Applicant #: 2001-201XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely. (6).

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



SI	TATE RESPONSE TO NOTIFICATION
	PHIS determination Please notify Ms. Carol Okada, culture, 701 Ilalo St., Honolulu, HI 96813. R and offers the following reasons:
Name of State official.	
Signature: (b) (6),	(b) (7)(C)
Date: 20 February 2001	
State: <u>Hawaii</u>	Rptloc01/R4



An Equal Opportunity Employer



Anmai and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown;

Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-15n

Applicant #: 2001-201XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient: Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official. Without & Bow
Signature: (b) (6), (b) (7)(C)
Date: 2/2/01
State: Rptloc01/R4

An Equal Opportunity Employer



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737.

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-15n

Applicant #: 2001-201XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jačkson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State official. NAMIA R NEGGO
Name of State official: AMIA RATE of Signature: (b) (6), (b) (7)(C)
Date: /- 29- 2001
State: Rptloc01/R4

An Equal Opposionity Employee

JAN 2 9 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release Notification no. 01-022-15n (2001-201XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

201

QK a

916367377085

038/038 00:08:28

******* -



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear(b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

May Jackson

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia. WA

R. Stoaks, PPQ, SCR, NR, Sacramento, CA



March 23, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085 . .
http://www.monsanto.com

Ms. Dianne Hatmaker Animal and Plant Health Inspection Services Biotechnology and Scientific Services 4700 River Road, Unit 147 Riverdale, MD

Dear Ms. Hatmaker;

In reviewing several acknowledged wheat notification, a typing error was discovered in line numbers. The line numbers should be TA_S0317, TA_S0635, TA_01081, TA_S2520, TA_S5450, TA_9240, TA_S0719, TA_S7535, TA_S7890, TA_S9512, TA_S10430. These lines were submitted with a hyphen rather than an underscore. The affected notifications were

Monsanto #	USDA#
2001-65XRAB	01-017-02n
2001-74XRAB	01-016-25n
2001-64XRAB	01-017-01n
2001-144XRAB	01-017-12n
2001-201XRAB	01-022-15n

If you have any additional questions, please call me my telephone number is (b) (6), (b) (7)(C)



cc: M. Isherwood Hawaii Dept. of Agric., Honolulu, HI

T. Sim, Kansas State Board of Agric. Topeka, Ks

M. Brown, Missouri Dept of Agric. Jefferson City, MO



April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

A #	Monsanto #
6-26n	2001-77XRAB
7-12n	2001-144XRAB
2-10n	2001-191XRAB
2-11n	2001-192XRAB
2-13n	2001-199XRAB
2-17n	2001-204XRAB
2-18n	2001-206XRAB
	6-26n 7-12n 2-10n 2-11n 2-13n 2-17n

Not a FOIA Deletion

Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (636-737-7191).



cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

(b) (6), (b) (7)(C)

SENDER

DAVID R. NELSON

DIVISION

PLANT PROTECTION

State Entomologist (701) 328-4765

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N

01-016-30N

01-022-10N

OR120018_BR_007626

700 'AN

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota

600 E. Boulevard Ave. Dept. 602 Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPO

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker

USDA-APHIS-PPO

Permits-Biotechnology

4700 River Road Riverdale MD 20737

FROM:

David R. Nelson (b) (6), (b)

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- 1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
- Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b) (7)(C)

OR120018 BR 007627

CC0 'AN

December 19, 2003

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Colycles

Re: Our Letter of 4/16/01 concerning the following notifications:

_		\	
K	<u>USDA#</u>		Monsanto #
//	01-016-26n	\	2001-77XRAB
/	01-017-12n	\	2001-144XRAB
	01-022-10n	1	2001-191XRAB
11	01-022-11n	ı	2001-192XRAB
11	01-022-13n	1	2001-199XRAB
\mathcal{U}_{\cdot}	01-022-15n	* <i>1</i>	2001-201XRAB
7	01-022-17n	1/	2001-204XRAB
\	01-022-18n		2001-106XRAB
\		/ .	

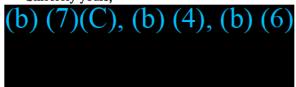
Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.



Please call if you require further information concerning this matter.

Sincerely yours,



December 19, 2003

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

<u>USDA#</u>	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

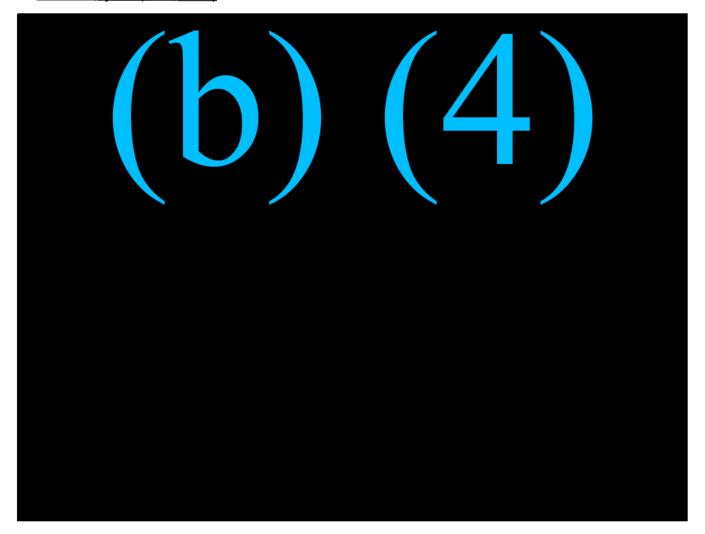
2001 Wheat Field Test Report USDA #01-022-15n Monsanto #2001-201XRAB

August 30, 2002

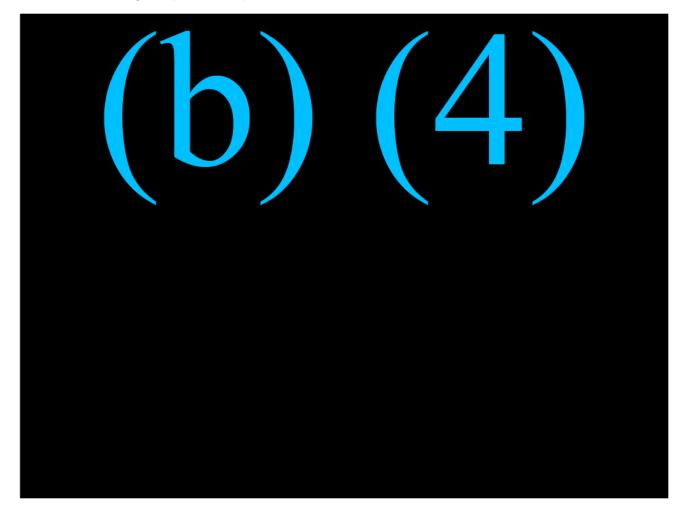
Biotech Field Compliance Team Monsanto Company

Location	County	State
2147307361	Cass County	ND
2147307363	La Moure County	ND
2147307362	Cass County	ND
2147307365	Wells County	ND

Cass County/ND (2147307361)

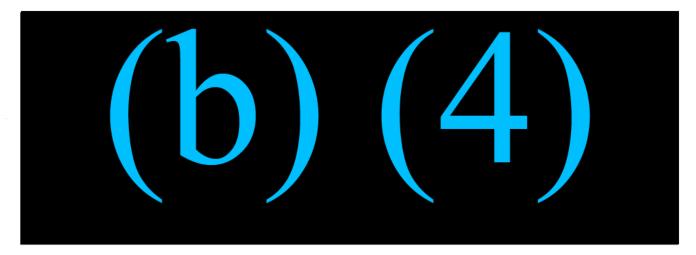


La Moure County/ND (2147307363)

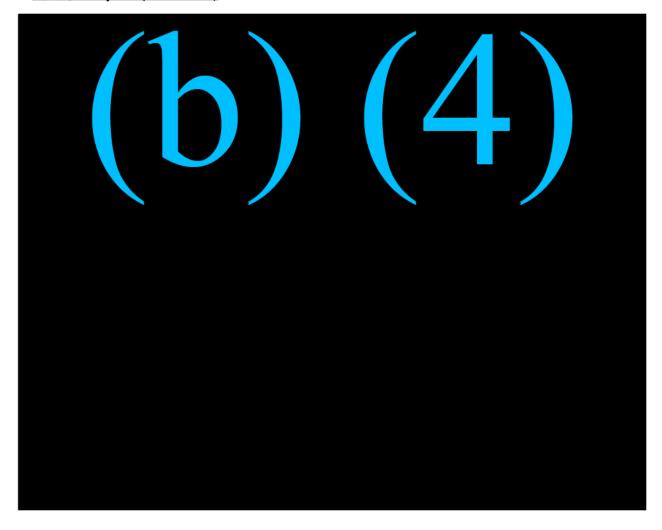


Cass County/ND (2147307362)





Wells County/ND (2147307365)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-022-15n Monsanto #2001-201XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	<u>State</u>
2147307361	Cass County	ND
2147307363	La Moure County	ND
2147307362	Cass County	ND
2147307365	Wells County	ND

Cass County/ND (2147307361)

Planting Date: 05/31/2001

Harvest Date: 09/04/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

La Moure County/ND (2147307363)

Planting Date: 05/03/2001

Harvest Date: 08/08/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Cass County/ND (2147307362)

Planting Date: 05/28/2001

Harvest Date: 08/23/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Wells County/ND (2147307365)

Planting Date: 05/05/2001

Harvest Date: 08/14/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Bp number: 01-022-16n

App number: 2001-202XRAB Begin movement: 2/17/01 Received: 1/22/01 End movement: 2/17/02 Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 5.00 Effective date: 2/21/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip:Chesterfield, MO Fax: 636-737-7085 Initial [] Assign Bp number and initial data entry [] Review by biotechnologist [✓ Letter of notification to State +cd -ex [] State response O/d Loc Site Reg Interstate *Dest*HI *WR * Interstate *Dest*KS *SCR * [Interstate *Dest*MO *SCR *] Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release *ND 1*SCR * [] I] Enter genes into database Letter of (acknowledgement/denial/withdraw [2/26/01] Enter final data into database 7. If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify reason for tandiness: (KS) did not respond



Monsanto Reference ID 2001-202XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-16n

1. USDA Reference Number

2. Applicant Reference Number 2001-202XRAB

3. Applicant/Responsible Party

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-202XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID 2001-202XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens 8. Introduction Interstate Movement and Release Ship up to 3000 pounds of wheat seed to and from each location. ORIGIN: **DESTINATION:** HI, KS, MO, ND HI, KS, MO, ND Ship From: HI Honolulu *[County/Province, HI, (b) (4) , U.S.A. CONTACT: (b) (4), (b) 300, Alea, Oahu, HI, 96701-3911, U.S.A., 808/486-5348] - CBI KS Sedgwick County/Province, KS(b) (4) USA CONTACT: b) (4), (b) (6), (b) (7)(C USA,] - CBI MO St. Louis County/Province, MO, (b) (4) CONTACT: MO, b) (4), (b) (6), (b) (7)(C)] - CBI ND Ward County/Province, ND, (b) (4 CONTACT: U.S.A. (b) (4), (b) (6), (b) (7)(C] - CBI

Page 3 of 6

Monsanto Reference ID

2001-202XRAB

Ship To: HI *[County/Province, HI, Honolulu (b) (4) U.S.A. CONTACT: (b) (4), (b) (6) (6) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)] - CBI KS (b) (4) Sedgwick County/Province, KS(b) (4)USA CONTACT: (b) (4), (b) (6), (b) (7)(C) USA,] - CBI MO St. Louis County/Province, MO(b) (4)] - CBI ND Ward County/Province, ND, (b) (4) CONTACT: U.S.A.,(b) (4), (b) (6), (b) (7)(C)] - CBI

Monsanto Reference ID

2001-202XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

(b) (4) Ward County/Province, ND, U.S.A., 5 acres.

] - CBI



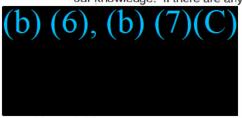
Monsanto Reference ID 2001-202XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-202XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-202XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-202XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID 2001-202XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-16n

1. USDA Reference Number

2. Applicant Reference Number 2001-202XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

b) (6), (b) (7)(C)_{@ monsanto.com}

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-202XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-202XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

Ship To:

Ш

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

Page 3 of 6

Monsanto Reference ID 2001-202XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

Monsanto Reference ID

2001-202XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Ward County/Province, ND, U.S.A., 5 acres



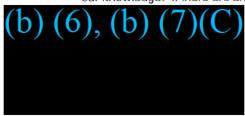
Monsanto Reference ID 2001-202XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001



Phone FAX EMail

Monsanto Reference ID 2001-202XRAB

monsanto.com

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE [314] 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-16n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-202XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

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5. Recipient

Wheat, Triticum aestivum

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Phenotype:

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Cultivar/Variety Bobwhite

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PV-TXGT10

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA

Complete from the form of the form from the

Monsanto Reference ID

2001-202XRAB

Page 3 of 6

7. M	lode of Transfo	prmation Disarmed Agrol	bacterium tumefaciens
8. In	. Introduction Interstate Movement and Release		ment and Release
S	ship up to 3000	pounds of wheat seed to and from	each location.
	PRIGIN: HI, KS, MO, N	ID	DESTINATION: HI, KS, MO, ND
Shi	ip From:		
	н		
[CBI Deleted] *Honolulu County/Province, H	I, U.S.A.
	KS		
1	CBI Deleted] *Sedgwick County/Province, K	KS, USA
	МО		9
]	CBI Deleted] *St. Louis County/Province, M	O. U.S.A
	ND		
Į	CBI Deleted] *Ward County/Province, ND, U	J.S.A.
Shi	р То:		
	н		
Ĭ	CBI Deleted] *Honolulu County/Province, HI	, U.S.A.

Color for for the first for th

Monsanto Reference ID 2001-202XRAB

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

Contract of the Contract of th

Monsanto Reference ID

2001-202XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

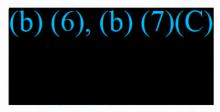
[CBI Deleted] -- Ward County/Province, ND, U.S.A., 5 acres



Monsanto Reference ID 2001-202XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813

January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION	
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following reasons:	
Name of State official:	
Signature:	_
Date:	
State: Rptloc01/R4	

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAB

Received:

January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE R	ESPONSE TO NOTIFICATION
State concurs with APHIS	determination.
State DOES NOT CONCUR and	offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

MD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION	
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following reason	ıs:
Name of State official:	
Signature:	
Date:	
State: Rptloc01/R4	

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAB

Effective: February 21, 2001

Received:

January 22, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787

or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

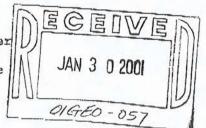
cc: R. Elliston, PPQ, Fort Collins, CO

,	STATE RESPONSE TO NOTIFICATION
Stat	e concurs with APHIS determination.
Stat	e DOES NOT CONCUR and offers the following reasons:
Name of Sta	te official:
Signature:_	
Date:	
State:	Rptloc01/R4



Animal and Plant Health Inapaction Service 4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813



January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

	STATE RESPONSE TO NOTIFICATION
X	State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo.St., Honolulu, HI 96813. State DOES NOT CONCUR and offers the following reasons:
Name	of State official: Carol L. Okada
Siana	(b) (6) , (b) (7) (C)

Date: 20 February 2001

State:

Hawaii

Rptloc01/R4



An Equal Opportunity Employer



Animai and Plant Health Inspection Service 4700 River Road Rivergale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Whea:

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilia (301) 734-8910 on or before the effective date.

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Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE	RESPONSE TO NOTIFICATION
State concurs with APHI	S determination.
	and offers the following reasons:
Name of State officials Mc	had E Bown
signature:_ (b) (6), (t)	o) (7)(C)
Date: 2/2/01	
State: MO	Rptloc01/R4



An Equal Opportunity Employer



Animal and Plant Health Inspection Service

4700 River Road Rivergale, MD 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-16n

Applicant #: 2001-202XRAE

Received: January 22, 2001

Effective: February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION
State concurs with APHIS determination.
State DOES NOT CONCUR and offers the following reasons:
Name of State designation DAVID A Challon
signature: (b) (6), (b) (7)(C)
Date: / 30-01
State: NO Rptloc01/R4



An Equal Opportunity Employer

JAN 3 0 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release Notification no. 01-022-16n (2001-202XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

S

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-022-16n

протокторного - COMM. JOURNAL- жикжижижижижижижий DATE FEB-23-2001 жижиж ТІМЕ 17:59 жижижий

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO. =497

ABBR NO. COMM. STN NO.

STATION NAME/TEL NO.

DURATION PAGES

001

OK

916367377085

038/038 00:08:28

– ******** –



Animal and Plant Health . Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

b) (6), (b) (7)(C) Dear

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

b) (6), (b)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia. WA R. Stoaks, PPQ. SCR, WR. Sacramento, CA



NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

(b) (6), (b) (7)(C)

SENDER

DAVID R. NELSON

State Entomologist

(701) 328-4765

DIVISION PLANT PROTECTION

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N

01-016-30N

01-022-10N

1.1

700 'AM

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota 600 E. Boulevard Ave. Dept. 602

Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPQ

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker

USDA-APHIS-PPO

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

(b) (6), (b) (7)

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- 1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
- Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b)(7)(C)CC

2001 Wheat Field Test Report USDA #01-022-16n Monsanto #2001-202XRAB

August 30, 2002

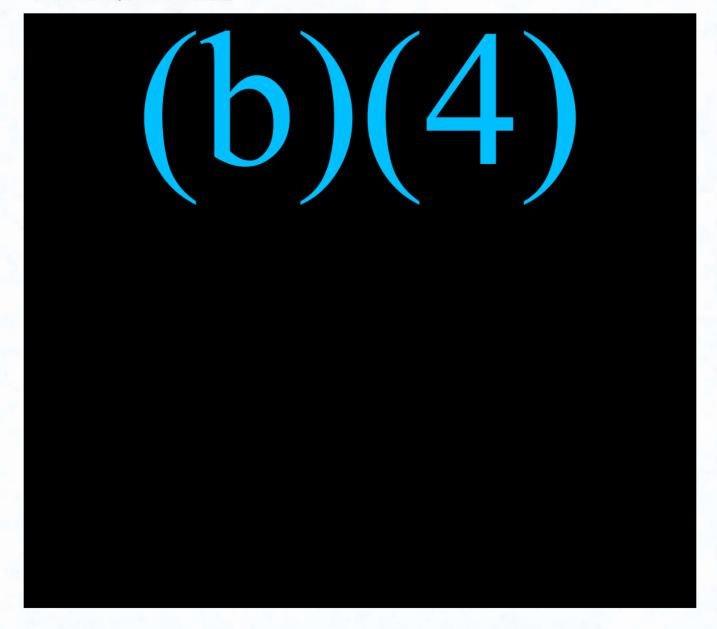
Biotech Field Compliance Team Monsanto Company

Location 115864463

County
Ward County

State ND

Ward County/ND (115864463)



(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-022-16n Monsanto #2001-202XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location

County

State

115864463

Ward County

ND

Ward County/ND (115864463)

Planting Date:

05/08/2001

Harvest Date:

08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bp number: 01-022-17n

App number: 2001-204XRAB Begin movement: 2/17/01 Received: 1/22/01 End movement: 2/17/02 Institution: Monsanto Begin release: 2/17/01 Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 15.00 Effective date: 2/21/01 CBI status: CBI Phenotype: HT - Glyphosate tolerant Comments: Resp person: Parsed name: Address1: Monsanto Company Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip: Chesterfield MO Telephone: Fax: 636-737-7085 -----------Initial Date [V] Assign Bp number and initial data entry [] Review by biotechnologist Letter of notification to State ed ex 4. [] State response O/d Loc Site Reg Interstate *Dest*HI *WR * Interstate *Dest*KS *SCR * [] Interstate *Dest*MO *SCR * 1 Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR * Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * Release *ND 3*SCR *] 1 Enter genes into database Letter of (acknowledgement) denial/withdraw 7. Enter final data into database If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify



Monsanto Reference ID 2001-204XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-17n

1. USDA Reference Number

2. Applicant Reference Number 2001-204XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

FAX

EMail

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 18, 2001

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

(b) (6), (b) (7)(C

b) (6), (b) (7)(C) monsanto.com

636/737-7085

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-204XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

(b)(4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-204XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

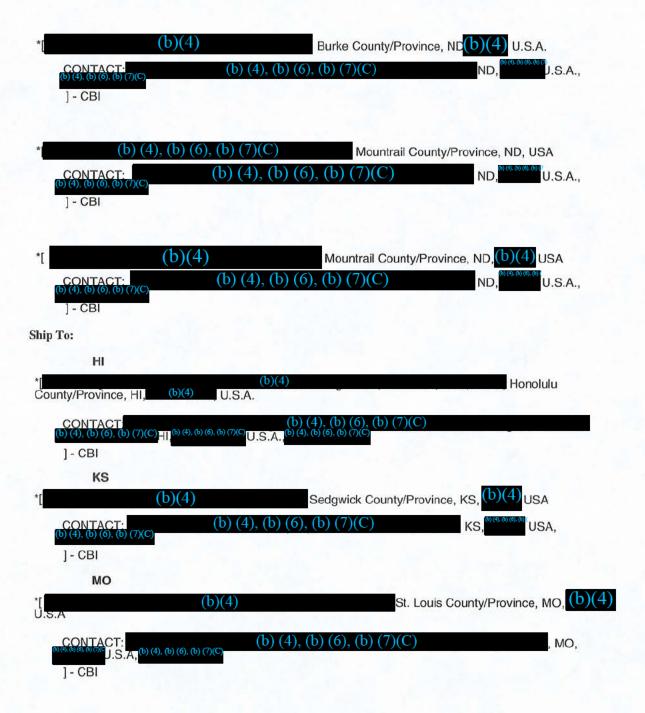
8. Introduction

Interstate Movement and Release

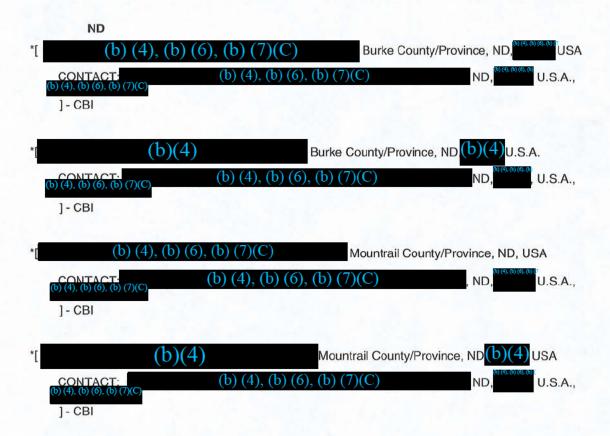
Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN: **DESTINATION:** HI, KS, MO, ND HI, KS, MO, ND Ship From: HI Honolulu *[County/Province, HI, CONTACT: b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A.,] - CBI KS (b)(4) Sedgwick County/Province, KS, - CBI MO St. Louis County/Province, MO, (b)(4) CONTACT: 63198, U.S.A, (b) (4), (b) (6), (b) (7)(C)] - CBI ND Burke County/Province, ND USA CONTACT:

Monsanto Reference ID 2001-204XRAB



Monsanto Reference ID 2001-204XRAB



Monsanto Reference ID

2001-204XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[(b) (4), (b) (6), (b) (7)(C) Burke County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C)

J.S.A. (b) (4), (b) (6), (b) (7)(C)

[CBI

[(b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C)
ND
(U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

] - CBI



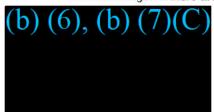
Monsanto Reference ID 2001-204XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-204XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-204XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-204XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID

2001-204XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-17n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-204XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX EMail 636/737-7085

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID 2001-204XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-204XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

Ш

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

Page 3 of 7

Monsanto Reference ID 2001-204XRAB

```
[ CBI Deleted ] -- *Mountrail County/Province, ND, USA
 [ CBI Deleted ] -- *Mountrail County/Province, ND, USA
Ship To:
          HI
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          ND
[ CBI Deleted ] -- *Burke County/Province, ND, USA
```

Monsanto Reference ID 2001-204XRAB

- [CBI Deleted] -- *Burke County/Province, ND, U.S.A.
- [CBI Deleted] -- *Mountrail County/Province, ND, USA
- [CBI Deleted] -- *Mountrail County/Province, ND, USA

Monsanto Reference ID

2001-204XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[CBI Deleted] -- Burke County/Province, ND, USA, 5 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 5 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 5 acres

Page 6 of 7



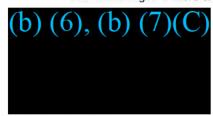
Monsanto Reference ID 2001-204XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001



Monsanto Reference ID 2001-204XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-17n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-204XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

63198

Cultivar/Variety Bobwhite

Monsanto Reference ID 2001-204XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

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Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Chilled I have been the Then D

Monsanto Reference ID

2001-204XRAB

7. M	ode	of	Trans	format	tion
------	-----	----	-------	--------	------

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Burke County/Province, ND, USA

CBI Deleted] -- *Burke County/Province, ND, U.S.A.

Page 3 of 7

Monsanto Reference ID 2001-204XRAB

```
[ CBI Deleted ] -- *Mountrail County/Province, ND, USA
 [ CBI Deleted ] -- *Mountrail County/Province, ND, USA
Ship To:
[ CBI Deleted ] -- *Honolulu County/Province, HI, U.S.A.
          KS
[ CBI Deleted ] -- *Sedgwick County/Province, KS, USA
          MO
[ CBI Deleted ] -- *St. Louis County/Province, MO, U.S.A
          ND
   CBI Deleted ] -- *Burke County/Province, ND, USA
```

CBINDENLE TED

Monsanto Reference ID 2001-204XRAB

- [CBI Deleted] -- *Burke County/Province, ND, U.S.A.
- [CBI Deleted] -- *Mountrail County/Province, ND, USA
- [CBI Deleted] -- *Mountrail County/Province, ND, USA



Monsanto Reference ID

2001-204XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[CBI Deleted] -- Burke County/Province, ND, USA, 5 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 5 acres

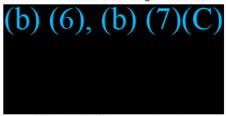
[CBI Deleted] -- Mountrail County/Province, ND, USA, 5 acres



Monsanto Reference ID 2001-204XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-17n Applicant #: 2001-204XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: N

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

18

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STAT	TE RESPONSE TO NOTIFICATION
State concurs with APF	HIS determination.
State DOES NOT CONCUR	and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281 January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-17n Applicant #: 2001-204XRAB

Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
State cond	curs with APHIS determination.
State DOES	S NOT CONCUR and offers the following reasons:
Name of State of:	ficial:
Signature:	
Date:	
State:	Rptloc01/R4

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-17n Applicant #: 2001-204XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE	E RESPONSE TO NOTIFICATION
State concurs with APHI	IS determination.
State DOES NOT CONCUR a	and offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020 January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-17n Applicant #: 2001-204XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: NI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

5

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
State	concurs with APHIS determination.
State	DOES NOT CONCUR and offers the following reasons:
Name of State	official:
Signature:	
Date:	
State:	Rpt1oc01/R4



Animal and Plant Health Inapection Service

4700 River Road Riverdale, MO 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-17n

Applicant #: 2001-204XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Moneanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPON	SE TO NOTIFICATION
State concurs with APHIS deter	mination.
State DOES NOT CONCUR and offe	rs the following reasons:
Name of State Official. DAVID	R No/307
Name of State Official. DAVID A Signature: (b) (6), (b) (7)	(C)
Date: 1-30-0/	
State: N	Rptloc01/R4



An Equal Opportunity Emisjoyee

JAN 3 0 2001



Animal and Plant Healin Inspection Service 4700 River Road Rivergale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-17n

Applicant #: 2001-204XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat:

Interstate destination: HI KS MO ND

Release destination:

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RES	SPONSE TO NOTIFICATION
State concurs with APHIS de	etermination.
Name of Stare official: Millac	E. Bour
(b) (6), (b) (7)(C)
Date: 2/2/01	
State: MD	Rptloc01/R4



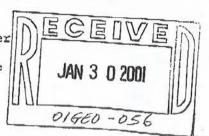
An Equal Opportunity Employer



Animal and Plant Health Inspection Service

4700 River Road Rivergale, MD 20737

Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813



January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-17n

Applicant #: 2001-204XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(6).

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

201	STY	TE RESPONSE	TO NOT	IFICATI	COM			
X	State concurs with As Hawaii Dept. of Agric State DOES NOT CONCUR	HIS determi	nation. Ilalo	Please St., Ho	notify	Ms. HI	Carol 96813	Okad (Oah
Name of	f State official	(b) (7)(C	1.	44044116	, reapor		_	
Date:_	20 February 2001							
State:	Hawaii		R	ptloc01	/R4			



An Equal Opportunity Employer

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release
Notification no. 01-022-17n (2001-204XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 (Oahu) upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

S

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-022-17n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO. =497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

991 OK

916367377885

038/038 00:08:28

- ******* -



Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339xRAB) Regulated article - Wheat Destinations - Hontana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ, SCR, WR, Sacramento, CA



NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

SENDER

DAVID R. NELSON

DIVISION PLANT PROTECTION

State Entomologist (701) 328-4765

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N

01-016-30N 01-022-10N

OR120018 BR 007714

700 'AN

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota 600 E. Boulevard Ave. Dept. 602 Bismarck, ND 58505-0020

TO:

James White

USDA-APHIS-PPQ

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737 (b) (6), (b) (7)

E. Diane Hatmaker

USDA-APHIS-PPQ

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- 1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
- 2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b)(7)(C)CC

OR120018 BR 007715

CCO 'ON



April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

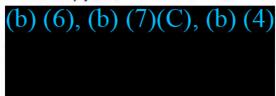
Re:	USDA#	Monsanto#
	01-016-26n	2001-77XRAB
	01-017-12n	2001-144XRAB
	01-022-10n	2001-191XRAB
	01-022-11n	2001-192XRAB
	01-022-13n	2001-199XRAB
	01-022-15n	2001-201XRAB
	01-022-17n	2001-204XRAB
	01-022-18n	2001-206XRAB

Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (6), (b) (7)(C), (b) (4)

Sincerely yours,



cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

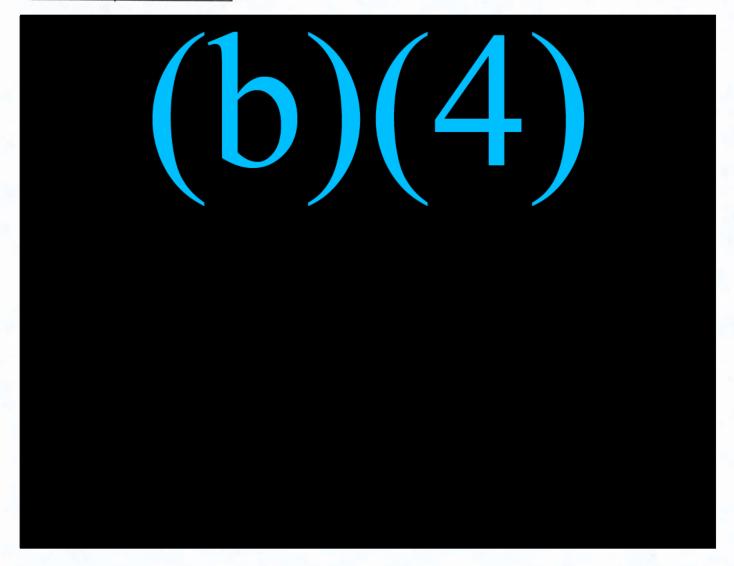
2001 Wheat Field Test Report USDA #01-022-17n Monsanto #2001-204XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	State	
2147307368	Burke County	ND	
7954	Mountrail County	ND	
2147303521	Mountrail County	ND	Not Planted

Burke County/ND (2147307368)





Mountrail County/ND (7954)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2001 Wheat Field Test Report USDA #01-022-17n Monsanto #2001-204XRAB

August 30, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	State	
2147307368	Burke County	ND	
7954	Mountrail County	ND	
2147303521	Mountrail County	ND	Not Planted

Burke County/ND (2147307368)

Planting Date: 05/09/2001

Harvest Date: 10/08/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Mountrail County/ND (7954)

Planting Date: 05/12/2001

Destruct Date: 06/27/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

December 19, 2003

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

http://www.monsanto.com

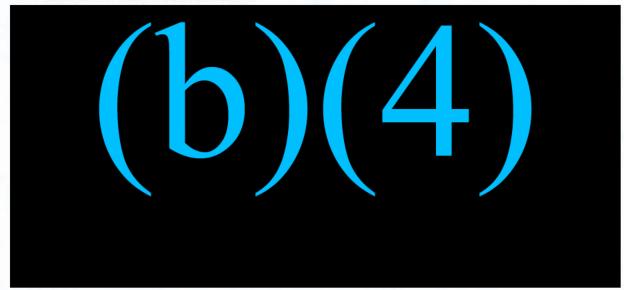
Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737 Colycles

Re: Our Letter of 4/16/01 concerning the following notifications:

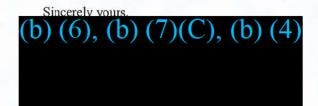
1	USDA#	Monsanto #
//	01-016-26n	2001-77XRAB
/ 1	01-017-12n	2001-144XRAB
/	01-022-10n	2001-191XRAB
	01-022-11n	2001-192XRAB
11	01-022-13n	2001-199XRAB
11	01-022-15n	2001-201XRAB
1	01-022-17n	2001-204XRAB
/	01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.



Please call if you require further information concerning this matter.



December 19, 2003

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

USDA#	Monsanto #
01-016-26n	2001-77XRAB
01-017-12n	2001-144XRAB
01-022-10n	2001-191XRAB
01-022-11n	2001-192XRAB
01-022-13n	2001-199XRAB
01-022-15n	2001-201XRAB
01-022-17n	2001-204XRAB
01-022-18n	2001-106XRAB

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI

Bp number: 01-022-18n

App number: 2001-206XRAB Begin movement: 2/17/01 End movement: Received: 1/22/01 2/17/02 Institution: Monsanto 2/17/01 Begin release: Recipient: Wheat End release: 2/17/02 Status: Pending Acre: 15.00 Effective date: 2/21/01 CBI status: CBI HT - Glyphosate tolerant Phenotype: Comments: Resp person: Parsed name: Monsanto Company Address1: Address2: 700 Chesterfield Parkway N. Address3: Address4: City/State/Zip Telephone: Fax: 636-737-7085 Initial Date Assign Bp number and initial data entry [V] Review by biotechnologist Letter of notification to State [] State response O/d Loc Site Reg Interstate *Dest*HI *WR Interstate *Dest*KS *SCR * Interstate *Dest*MO *SCR * Interstate *Dest*ND *SCR * Interstate *Orig*HI *WR Interstate *Orig*KS *SCR * Interstate *Orig*MO *SCR * Interstate *Orig*ND *SCR * *ND Release 3*SCR *] 5. Enter genes into database Letter of (acknowledgement)denial/withdraw 7. Enter final data into database

8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify

reason for tardiness: (KS) did not respond



Monsanto Reference ID

2001-206XRAB

J1-206XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-206XRAB

3. Applicant/Responsible Party

Phone (b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-206XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 ---

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-206XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN: DESTINATION: HI, KS, MO, ND HI, KS, MO, ND Ship From: HI Honolulu County/Province, HI] - CBI KS (b)(4)Sedgwick County/Province, KS (b)(4), USA CONTACT; b) (4), (b) (6), (b) (7)(C)] - CBI MO St. Louis County/Province, MO, (b)(4) CONTACT: 1 - CBI ND *[58105, U.S.A Cass County/Province, ND, CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) 1 - CBI

Page 3 of 6

Monsanto Reference ID

2001-206XRAB

Ship To: HI *[County/Province, HI, (b)(4)Honolulu (b)(4)U.S.A. CONTACT: (b) (4), (b) (6), (b) (7)(C) HII (6) (4), (b) (6), (b) (7)(C) U.S.A.] - CBI KS (b)(4)Sedgwick County/Province, KS (b)(4) USA CONTACT: (b) (4), (b) (6), (b) (7)(C) USA,] - CBI MO St. Louis County/Province, MO, (b)(4) CONTACT: U.S.A, (b) (4), (b) (6), (b) (7)(C)] - CBI ND *[(b)(4), U.S.A (b)(4)Cass County/Province, ND, CONTACT: ND, (b) (4), (b) (6), (b) (7)(C) U.S.A,(b) (4), (b) (6), (b) (7)(C)

] - CBI

Monsanto Reference ID 2001-206XRAB Release Site: NUMBER OF STATES/TERRITORIES AND SITES: ND (3) ND (b)(4)Cass County/Province, ND, U.S.A, 5 acres.] - CBI Cass County/Province, ND, USA, 5 acres.] - CBI Cass County/Province, ND, USA, 5 acres. (b) (4), (b) (6), (b) (7)(C) (U.S.A) (b) (4), (b) (6), (b) (7)(C) RESPONSIBLE PERSON/RESEARCHER] - CBI



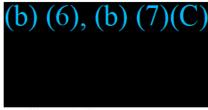
Monsanto Reference ID 2001-206XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" f("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. <u>Id.</u> at 530; <u>National Parks & Conservation Association v. Kleppe</u>, 547 F.2d 673, 679 (D.C.Cir. 1976); <u>Miami Herald Pub. Co. v. U.S. Small Business Administration</u>, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification Notification 2001-206XRAB Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, <u>Critical Mass Energy Project v. NRC</u>, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. CBI Justification Notification 2001-206XRAB Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification Notification 2001-206XRAB Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



Monsanto Reference ID

2001-206XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-206XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX EMail 636/737-7085 (b) (6) (b) (7)(

b) (6), (b) (7)(C) monsanto.com

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085

http://www.monsanto.com

January 18, 2001

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID 2001-206XRAB

designation of transformed line:

33391

Constructs:

PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-206XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

HI, KS, MO, ND

HI, KS, MO, ND

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

Page 3 of 6

Monsanto Reference ID 2001-206XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

Monsanto Reference ID

2001-206XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[CBI Deleted] -- Cass County/Province, ND, U.S.A, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres



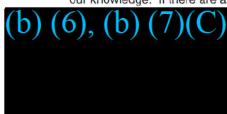
Monsanto Reference ID 2001-206XRAB

9. Certification

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001



Phone FAX

EMail

Monsanto Reference ID 2001-206XRAB MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

January 18, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-022-18n

- 1. USDA Reference Number
- 2. Applicant Reference Number 2001-206XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

63198

4. Duration of Introduction

Interstate Movement and Release

February 17, 2001 - February 17, 2002

636/737-7085

b) (6), (b) (7)(C)@ monsanto.com

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

Monsanto Reference ID

2001-206XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2001-206XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens 8. Introduction Interstate Movement and Release Ship up to 3000 pounds of wheat seed to and from each location. ORIGIN: DESTINATION: HI, KS, MO, ND HI, KS, MO, ND Ship From: HI [CBI Deleted] -- *Honolulu County/Province, HI, U.S.A. KS CBI Deleted] -- *Sedgwick County/Province, KS, USA MO [CBI Deleted] -- *St. Louis County/Province, MO, U.S.A ND [CBI Deleted] -- *Cass County/Province, ND, U.S.A Ship To:

OR120018_BR_007744

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

HI

Page 3 of 6



Monsanto Reference ID 2001-206XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

Monsanto Reference ID

2001-206XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (3)

ND

[CBI Deleted] -- Cass County/Province, ND, U.S.A, 5 acres

CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

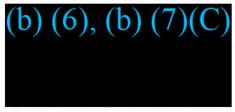
[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres



Monsanto Reference ID 2001-206XRAB Monsanto Company 700 Chesterfield Pkwy North Chesterfield, Missouri 63198 PHONE (314) 694-1000 FAX (636) 737-7085 http://www.monsanto.com

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.



Monsanto Company January 18, 2001 Mr. Myron Isherwood Jr., Manager Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813 January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-18n Applicant #: 2001-206XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

S

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESE	PONSE TO NOTIFICATION
State concurs with APHIS det	termination.
State DOES NOT CONCUR and of	ffers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rpt1oc01/R4

Mr. Tom Sim IV, Administrator Plant Protection and Weed Control Section Kansas State Board of Agriculture 901 S. Kansas Avenue Topeka, KS 66612-1281

January 23, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-18n Applicant #: 2001-206XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: NE

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

15

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIF	ICATION
State concurs with APHIS determination.	
State DOES NOT CONCUR and offers the following	owing reasons:
Name of State official:	
Signature:	والودة الراكا <u>شيدا</u>
Date:	
State:Rpt	loc01/R4

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-18n Applicant #: 2001-206XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

S

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

	STATE RESPONSE TO NOTIFICATION
State	e concurs with APHIS determination.
State	DOES NOT CONCUR and offers the following reasons:
Name of Stat	ce official:
Signature:_	
Date:	
State:	Rptloc01/R4

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020 January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-022-18n Applicant #: 2001-206XRAB Received: January 22, 2001 Effective: February 21, 2001

Institution: Monsanto Recipient: Wheat

Interstate destination: HI KS MO ND

Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPO, Fort Collins, CO

A SA	2000 C 10552
STATE R	RESPONSE TO NOTIFICATION
State concurs with APHIS	determination.
State DOES NOT CONCUR and	d offers the following reasons:
Name of State official:	
Signature:	
Date:	
State:	Rptloc01/R4



Animal and Plant Health Inapaction Service

4700 River Road Riverdale, MD 20737

Mr. Michael Brown Plant Industries Division Missouri Department of Agriculture 1616 Missouri Boulevard Jefferson City, MO 65102

January 23, 2001

Dear Mr. Brown:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-18n

Applicant #: 2001-206XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(6), (b) (7

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

CC: R. Elliston, PPQ, Fort Collins, CO

STATE RESPO	DNSE TO NOTIFICATION
State concurs with APHIS dete	ermination.
State DOES NOT CONCUR and off	
Name of State officials Wich	E. Bow
$_{\text{signature:}}$ (b) (6), (b) (7)(C)
Date: 2/2/01	
State: Mo	Rptloc01/R4

APHS - Protecting American Agriculture

An Equal Opportunity Employee

FEB 5 2001



Animai and Plant Health Inspection Service

4700 River Road Riverdala, MD 20737

Mr. David R. Nelson, State Entomologist North Dakota Department of Agriculture 600 East Boulevard, 6th Floor Bismarck, ND 58505-0020

January 23, 2001

Dear Mr. Nelson:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number

01-022-18n

Applicant #: 2001-206XRAB

Received:

January 22, 2001

Effective:

February 21, 2001

Institution: Monsanto

Recipient:

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

/	STATE RESPONSE TO NOTIFICATION
State concurs wit	h APHIS determination.
State DOES NOT CO	NCUR and offers the following reasons:
Name of State official:	DAVID RNR (JOT
signature: (b) (6), ((b) (7)(C)
Date: [-3:-0]	
State: NO	Rptloc01/R4

APPAS - Preserving American Agriculture

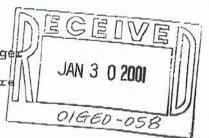
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JAN 3 0 2001



Animai and Plant Heath Inspection Service 4700 River Road Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manage Plant Quarantine Branch Hawaii Department of Agriculture 701 Ilalo Street Honolulu, HI 96813



January 23, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-022-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number Received:

01-022-18n

Applicant #: 2001-205XRAB

January 22, 2001

Institution: Monsanto

Effective: Recipient:

February 21, 2001

Wheat

Interstate destination: HI KS MO ND

Release destination:

ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE	RESPONSE	TO	NOTIFICATION

State concurs with APHIS determination Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813. X State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol I

Signature:

Date: 20 February 2001

State: Hawaii

Rptloc01/R4

PMS - Protecting American Agricultura

An Equal Opportunity Employer

NORTH DAKOTA DEPARTMENT OF AGRICULTURE 600 EAST BOULEVARD BISMARCK ND 58505-0020

PHONE 701 328-4765

FAX 701 328-4567

FACSIMILE MESSAGE

DATE:

April 17, 2001

FAX NUMBER:

301 734-8910

COMPANY NAME: .

USDA APHIS - BIOTECHNOLOGY SCIENTIFIC SERVICES

CITY AND STATE

RIVERDALE MD

ATTENTION

DIANNE HATMAKER 301 734-5787

TRANSMISSION CONSISTS OF

PAGE INCLUDING COVER PAGE.

PLEASE ADVISE IF TRANSMISSION IS NOT WELL RECEIVED. IF YOU HAVE ANYPROBLEMS OR QUESTIONS, PLEASE CALL THE NORTH DAKOTA DEPARTMENT OF AGRICULTURE AT (701) 328-2231.

(b) (6), (b) (7)(C)

SENDER

DAVID R. NELSON

DIVISION

PLANT PROTECTION

State Entomologist (701) 328-4765

Attached are responses to notifications.

I would like to see these conditions on the attached letter applied to several notifications that were previously replied to. They are:

01-022-18N

01-022-16N

01-022-17N

01-022-15N

01-022-11N

01-022-13N 01-016-30N

01-022-10N

P. 1

AGRICULTURE COMMISSIONER ROGER JOHNSON



PHONE (701) 328-2231

(800) 242-7535

FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE State of North Dakota 600 E. Boulevard Ave. Dept. 602 Bismarck, ND 58505-0020

(6), (b)

TO:

James White

USDA-APHIS-PPQ

Biotechnology Risk Assessment

4700 River Road

Riverdale MD 20737

E. Diane Hatmaker

USDA-APHIS-PPQ

Permits-Biotechnology

4700 River Road

Riverdale MD 20737

FROM:

David R. Nelson

DATE:

April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

- Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
- 2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
- 3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

(b) (6), (b) (7)(C) CC

February 21, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Pkwy N St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been <u>acknowledged</u> and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release Notification no. 01-022-18n (2001-206XRAB) Regulated article - Wheat Destinations - Hawaii, Kansas, Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

 Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

181

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessment Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI T. Sim, Kansas State Board of Agric., Topeka, KS

- M. Brown, Missouri Dept of Agric., Jefferson City, MO
- D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
- R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-022-18n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO. COMM. ABBR NO.

STATION NAME/TEL NO.

PAGES DURATION

001

OK &

916367377085

038/038 00:08:28

- ******* -

- www.www.



Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company 700 Chesterfield Parkway N. St. Louis, MO 63198

Dear (b) (6), (b) (7)(C

Your notification request has been acknowledged and may be executed according to 7 CPR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release Notification no. 01-037-12n (2001-339XRAB) Regulated article - Wheat Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist Biotechnology Program Operations Permits and Risk Assessments Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT

T. Wessels, Washington Dept. of Agric., Olympia, WA

R. Stoaks, PPQ. SCR, WR. Sacramento, CA



An Equal Opportunity Employer



April 16, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

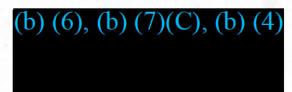
Re:	USDA#	Monsanto #
	01-016-26n	2001-77XRAB
	01-017-12n	2001-144XRAB
	01-022-10n	2001-191XRAB
	01-022-11n	2001-192XRAB
	01-022-13n	2001-199XRAB
	01-022-15n	2001-201XRAB
	01-022-17n	2001-204XRAB
	01-022-18n	2001-206XRAB

Dear Ms. Hatmaker:

Due to an error, transformed line #33512 (PV-TXGT12) was inadvertently omitted from the notifications listed above. Please include this line number in the above notifications. This line had been included in notification 00-195-06n (2000-520XRAB), which covered the trial that produced the seed for shipment and release under the notifications listed above.

Thank you for your assistance with this matter. Please call if you require further information (b) (6), (b) (7)(C), (b) (4)

Sincerely yours,



cc: Dr. Ralph Stoaks USDA, APHIS, PPQ

CONFIDENTIAL

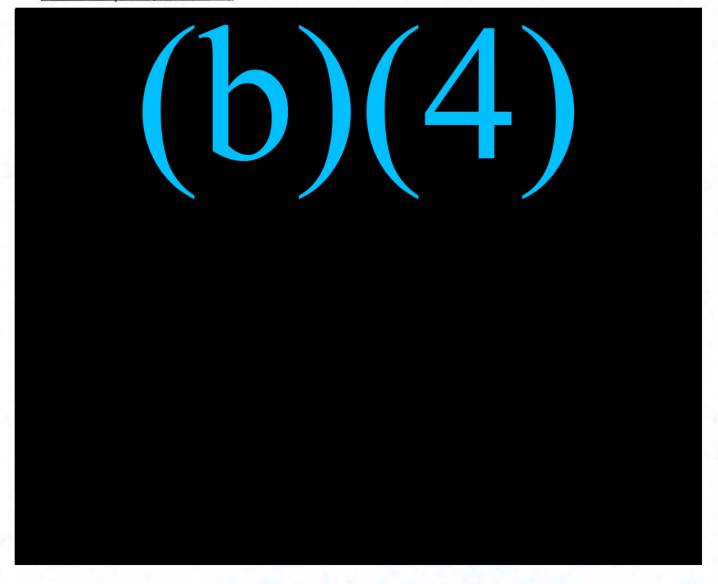
2001 Wheat Field Test Report USDA #01-022-18n Monsanto #2001-206XRAB

September 26, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	State	
635	Cass County	ND	Not Planted
2147307378	Cass County	ND	
2147303287	Cass County	ND	Not Planted

Cass County/ND (2147307378)



(b)(4)

2001 Wheat Field Test Report USDA #01-022-18n Monsanto #2001-206XRAB

September 26, 2002

Biotech Field Compliance Team Monsanto Company

Location	County	<u>State</u>	
635	Cass County	ND	Not Planted
2147307378	Cass County	ND	
2147303287	Cass County	ND	Not Planted

Cass County/ND (2147307378)

Planting Date: 05/31/2001

Harvest Date: 08/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. I.L.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, and information is appropriately protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

REDACTED

December 19, 2003

MONSANTO COMPANY 700 CHESTERFIELD PKWY NORTH CHESTERFIELD, MISSOURI 63198 http://www.monsanto.com

Mr. Juan A. Roman Team Leader Permitting and Notification USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737

Re: Our Letter of 4/16/01 concerning the following notifications:

USDA#	Monsanto #	
01-016-26n	2001-77XRAB	
01-017-12n	2001-144XRAB	
01-022-10n	2001-191XRAB	
01-022-11n	2001-192XRAB	
01-022-13n	2001-199XRAB	
01-022-15n	2001-201XRAB	
01-022-17n	2001-204XRAB	
01-022-18n	2001-106XRAB	

Dear Mr. Roman:

This letter provides an update to our previous letter of 4/16/01 concerning the addition of a construct and line number to the notifications listed above.

[CBI-DELETED]-CBI

Please call if you require further information concerning this matter.

Sincerely yours,

[CBI-DELETED]-CBI